

The Honorable Benjamin H. Settle

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA**

DREW MACEWEN, *et al.*,

Plaintiffs,

vs.

GOVERNOR JAY INSLEE, in his
official capacity as the Governor of
Washington,

Defendant.

NO. 3:20-cv-05423-BHS

DECLARATION OF
ZACHARY PEKELIS JONES IN
SUPPORT OF DEFENDANTS'
RESPONSE TO MOTION FOR
PRELIMINARY INJUNCTION

I, Zachary Pekelis Jones, declares as follows:

1. I am an Assistant Attorney General in the Complex Litigation Division of the Washington Attorney General's Office. In that capacity, I represent Washington Governor Jay Inslee in the above-captioned matter. I have personal knowledge of the facts of and pleadings in each matter and am competent to make this declaration.

2. I also represent the Governor in several other cases challenging the Proclamations he has issued in response to the COVID-19 pandemic, including *Akesson v. Inslee*, No. 20-2-00076-38 (Whitman Cty. Super. Ct.), *Cuevas v. Inslee*, No. 20-2-00352-04 (Chelan Cty. Super. Ct.), and *Simper v. Inslee*, No. 20-2-00369-21 (Thurston Cty. Super. Ct.). (Although originally filed in Lewis County Superior Court, *Simper* was transferred to Thurston County pursuant to the Governor's CR 12(b)(3) Motion to Change Venue.) Counsel for Plaintiffs here also represent

DECLARATION OF
ZACHARY PEKELIS JONES IN
SUPPORT OF DEFENDANT'S
RESPONSE TO MOTION FOR
PRELIMINARY INJUNCTION
NO. 3:20-CV-05423-BHS

1 the plaintiffs in those other three cases. Plaintiffs' counsel also represented the plaintiffs in *Sutton*
 2 *v. Inslee*, No. 20-2-00139-09 (Douglas Cty. Super. Ct.), another lawsuit challenging the
 3 Proclamations that plaintiffs voluntarily dismissed on June 1, 2020, in which I also represented
 4 the Governor. I am therefore familiar with the facts of and the pleadings in those other matters.

5 3. Attached hereto as Exhibit A is a true and correct copy of the Complaint in
 6 *Akesson v. Inslee*, No. 20-2-00076-38 (Whitman Cty. Super. Ct.).

7 4. Attached hereto as Exhibit B is a true and correct copy of the Complaint in *Cuevas*
 8 *v. Inslee*, No. 20-2-00352-04 (Chelan Cty. Super. Ct.).

9 5. Attached hereto as Exhibit C is a true and correct copy of the Complaint in *Sutton*
 10 *v. Inslee*, No. 20-2-00139-09 (Douglas Cty. Super. Ct.).

11 6. Attached hereto as Exhibit D is a true and correct copy of the Complaint in *Simper*
 12 *v. Inslee*, No. 20-2-00369-21 (Thurston Cty. Super. Ct.).

13 7. Attached hereto as Exhibit E is a true and correct copy of the excerpted transcript
 14 of the deposition of Dr. Malcolm Butler, taken on June 8, 2020 in the matter of *Cuevas v. Inslee*,
 15 No. 20-2-00352-04 (Chelan Cty. Super. Ct.).

16 8. Attached hereto as Exhibit F is a true and correct copy of an email from Chelan-
 17 Douglas Health District Administrator Barry Kling to Chelan County Sheriff Brian Burnett.

18 9. Attached hereto as Exhibit G is a true and correct copy of an email thread
 19 between, inter alia, Dr. Malcolm Butler and Marc Straub, which was used as Exhibit 5 in the
 20 deposition of Dr. Butler.

21 10. Attached hereto as Exhibit H is a true and correct copy of an email from Dr.
 22 Malcolm Butler to Marc Straub, which was used as Exhibit 6 in the deposition of Dr. Butler.

23 11. Attached hereto as Exhibit I is a true and correct copy of a scientific journal
 24 article, John Iskander *et al.*, *Pandemic Influenza Planning, United States, 1978–2008*, 19
 25 *Emerging Infectious Diseases* 879 (June 2013), which is available online at
 26 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3713824/>.

12. Attached hereto as Exhibit J is a true and correct copy of an official government document, Homeland Security Council, *National Strategy for Pandemic Influenza* (Nov. 2005), which is available online at <https://www.cdc.gov/flu/pandemic-resources/pdf/pandemic-influenza-strategy-2005.pdf>.

13. Attached hereto as Exhibit K is a true and correct copy of an official government document, Homeland Security Council, *National Strategy for Pandemic Influenza Implementation Plan* at 115, 84 (May 2006), which is available online at <https://www.cdc.gov/flu/pandemic-resources/pdf/pandemic-influenza-implementation.pdf>.

14. Attached hereto as Exhibit L is a true and correct copy of an official government document, U.S. Dep't of Health and Human Services, *HHS Pandemic Influenza Plan* at I-5 (Nov. 2005), which is available online at <https://www.hsdh.org/?view&did=457389>.

15. Attached hereto as Exhibit M is a true and correct copy of an official government document, Sarah A. Lister, Cong. Res. Serv., *Pandemic Influenza: Appropriations for Public Health Preparedness and Response*, (Jan. 23, 2007), which is available online at <https://fas.org/sgp/crs/misc/RS22576.pdf>.

16. Attached hereto as Exhibit N is a true and correct copy of an official government document, CDC, *Pandemic Influenza Guidance Supplement to the 2006 Public Health Emergency Preparedness Cooperative Agreement Phase II*, July 10, 2006, which is available online at <https://www.cdc.gov/cpr/documents/coopagreement-archive/fy2006/phase2-panflu-guidance.pdf>.

17. Attached hereto as Exhibit O is a true and correct copy of an official government document, HHS Office of Inspector General, Memorandum Report from Inspector General Daniel R. Levinson to Dr. Julie L. Gerberding Re: Laboratory Preparedness for Pandemic Influenza (Oct. 24, 2007), which is available online at <https://oig.hhs.gov/oei/reports/oei-04-07-00670.pdf>.

1 I declare under the penalty of perjury of the laws of the State of Washington and the
2 United States that the foregoing statement is true and correct.

3 DATED this 15th day of June, 2020, at Seattle, Washington.
4

5 s/ Zachary Pekelis Jones
6 ZACHARY PEKELIS JONES, WSBA #44557
7 Assistant Attorney General
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26

Exhibit A

☒ EXPEDITE☒ No hearing set☐ Hearing is set

Date: _____

Time: _____

Judge: HON. GARY LIBEY

STATE OF WASHINGTON
WHITMAN COUNTY SUPERIOR COURT

KEVIN AKESSON,

Plaintiff,

v.

COMPLAINT

JAY INSLEE, IN HIS OFFICIAL CAPACITY
AS GOVERNOR,*Defendant.*

Plaintiff alleges as follows:

I. PRELIMINARY STATEMENT

1. COVID-19 is a novel virus that can cause serious illness and can spread easily from person to person.

2. Chapter 72.06 RCW provides direction for how to prepare for and respond to a “novel virus” such as COVID-19. It places responsibility for doing so at the local level.

3. Now that it is clear that COVID-19 will not overwhelm hospital and other health care resources in Whitman County, there is no longer a “disaster” or any other emergency justifying the issuance of orders pursuant to RCW 43.06.220.

II. JURISDICTION AND VENUE

4. This Court has jurisdiction over the subject matter of this lawsuit.

5. Kevin Akesson is a resident of Whitman County. Therefore, venue is proper with respect to the defendant pursuant to RCWA 4.92.010(1).

III. PARTIES

6. Kevin Akesson is a resident of Whitman County, Washington.

7. Akesson and his family are unable to attend church services.

8. Akesson's church board has decided to comply with the Governor's Proclamations and only provide non-attended, on-line services only.

9. Akesson believes that his church and all churches are essential in times of real or perceived emergency to provide Christian worship, proper perspective, spiritual guidance, Biblical instruction, fellowship, hope, confidence and stability.

10. Because Akesson has very limited, intermittent internet capability by smartphone only at his rural house, his family is unable to attend even the on-line church services as a family.

11. Akesson's church is able to provide in-person worship services safely—for example by maintaining sufficient distance between worshippers and by providing disinfecting supplies as well as facemasks.

12. Due to local fitness center closures, Akesson's family have been unable to perform normal fitness routines, negatively impacting their health.

13. Akesson's local library is a major resource that he and his family use for homeschooling their children, for internet access, and for general social and intellectual improvement. This resource has not been available to Akesson due to the proclamations that closed the libraries.

14. Akesson is politically active. Political meetings have been cancelled or held on-line only to comply with the proclamations.

15. Akesson has inadequate internet access to attend the on-line meetings.

16. The Proclamations have limited Akesson's ability to peaceably assemble and petition the government for redress of the foregoing grievances.

17. Akesson's political party county convention was held on-line to comply with the proclamations preventing large gathering.

1 18. After his political party elected him to the county convention through the precinct
2 caucus process, Akesson was unable to attend the county convention due to inadequate access to
3 the internet.

4 19. Three of Akesson's children take part in monthly Bible Quizzing competitions
5 locally, regionally and nationally. The local and regional competitions were cancelled due to the
6 proclamations.

7 20. These are significant socialization events for Akesson's family.

8 21. Akesson's senior high school son's spring baseball season was cancelled by the
9 proclamations.

10 22. The softball seasons for Akesson's three daughters have been cancelled due to the
11 proclamations.

12 23. The foregoing spring sports activities are major social and recreational activities for
13 Akesson's family, all lost due to the proclamations.

14 24. Jay Inslee is the Governor of the State of Washington.

15 **IV. FACTUAL ALLEGATIONS**

16 **THE NATURE OF COVID-19**

17 25. COVID-19 is caused by a virus.¹

18 26. The COVID-19 virus first began to infect humans in 2019.²

19 27. The COVID-19 virus is a new virus within the meaning of RCW 70.26.010(1).

20 28. COVID-19 can cause serious illness.³

21 29. COVID-19 spreads easily from person to person.⁴

25 ¹ <https://www.cdc.gov/coronavirus/2019-ncov/faq.html#Coronavirus-Disease-2019-Basics>

26 ² *Id.*

27 ³ *Id.*

⁴ *Id.*

30. Merriam-Webster defines “flu” as “1: influenza” and “2: any of several virus diseases marked especially by respiratory or intestinal symptoms.”⁵

31. Merriam-Webster defines “influenza” as “1a : an acute, highly contagious, respiratory disease caused by any of three orthomyxoviruses . . .” and “1b: any of various human respiratory infections of undetermined cause —not used technically.”⁶

32. Merriam-Webster adds “Note: All types of influenza are commonly called “‘the flu.’”⁷

33. COVID-19 is a viral disease.⁸

34. The COVID-19 virus is a coronavirus.⁹

35. COVID-19 is marked especially by respiratory symptoms.¹⁰

36. COVID-19 is an acute, highly contagious respiratory disease.¹¹

37. COVID-19 satisfies the common English definition of “flu” and “influenza” as those words are used in RCW 70.26.010, whether or not the virus falls within the same scientific classification taxonomy of seasonal influenza, the Asian flu of 1957-58, the Hong Kong flu in 1968-69, or the 2006 Avian or bird flu.

38. The first case of COVID-19 was confirmed in Snohomish County, Washington on January 21, 2020.¹²

39. Prior to January 21, 2020 no case had been reported anywhere else in the United States.

⁵ <https://www.merriam-webster.com/dictionary/flu>

⁶ <https://www.merriam-webster.com/dictionary/influenza>

⁷ *Id.*

⁸ *Id.*

⁹ *See supra* note 1.

¹⁰ <https://www.cdc.gov/coronavirus/2019-ncov/faq.html#Symptoms-&-Testing>

¹¹ https://wwwnc.cdc.gov/eid/article/26/7/20-0282_article

¹² <https://www.snohd.org/495/COVID-19-General-Information>

THE IHME COVID-19 MODELS

40. The Institute for Health Metrics and Evaluation (IHME) is an independent global health research center at the University of Washington.¹³

41. IHME has modeled the likely course of COVID-19 in Washington state, including predictions of cases, deaths, and use of health care resources, importantly including hospital beds, intensive care unit beds, and invasive ventilators.¹⁴

42. IHME's first predictive model was issued on March 25, 2019.¹⁵

43. IHME subsequently issued updated models on March 26, 2020; March 27, 2020; March 29, 2020; March 30, 2020; March 31, 2020; April 1, 2020; April 5, 2020; April 7, 2020; April 8, 2020; April 10, 2020; April 13, 2020; April 17, 2020; April 21, 2020; April 22, 2020; April 27, 2020; April 28, 2020; April 29, 2020; May 4, 2020; and May 8, 2020.¹⁶

44. The March 25 IHME model and all subsequent IHME models are predicated on various assumptions, including that Washington practiced "social distancing," shorthand for the various mandates of the Proclamations.¹⁷

45. The March 25 IHME model predicted between 312 and 2710 Washington State deaths due to COVID-19, with a mean estimate of 1429 deaths.¹⁸

46. The March 25 IHME model also predicted that by April 14, 2020, at worst Washington state could have a shortage of available hospital beds of as many as 97 beds that day, increasing to an unmeetable need of over 635 beds by April 23, and declining thereafter until there was no predicted shortage by May 3.¹⁹

¹³ <http://www.healthdata.org/about>

¹⁴ <http://www.healthdata.org/covid>

¹⁵ <http://www.healthdata.org/covid/data-downloads>

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ <https://ihmecovid19storage.blob.core.windows.net/archive/2020-03-25/ihme-covid19.zip>

¹⁹ *Id.*

1 47. The March 30 IHME model predicted between 462 and 3,239 Washington state
2 deaths due to COVID-19, with a mean estimate of 1621 deaths.²⁰

3 48. The March 30 IHME model also predicted that by April 13, 2020, at worst
4 Washington state could have a shortage of available hospital beds of as many as 37 beds that day,
5 increasing to an unmeetable need of over 1270 beds by April 29, and declining thereafter until there
6 was no predicted shortage by May 16.²¹

7 49. The April 1 IHME model predicted between 468 and 1636 Washington state deaths
8 due to COVID-19, with a mean estimate of 978 deaths.²²

9 50. The April 1 IHME model no longer predicted that Washington would face any
10 shortage of total hospital beds.²³

11 51. The April 1 IHME model did predict that, in a worst case scenario, Washington
12 would face a shortage of available ICE beds beginning March 30, 2020 of 23 beds, peaking with a
13 shortage on April 14 of 275 beds, and continuing through May 4, 2020.²⁴

14 52. The April 5 IHME model predicted between 557 and 741 Washington state deaths
15 due to COVID-19, with a mean estimate of 632 deaths.²⁵

16 53. The April 5 IHME model no longer predicated a potential shortage of either
17 hospital beds or ICU beds.²⁶

18 54. No subsequent IHME model has predicted a potential shortage of any needed
19 hospital resource.²⁷

20 ²⁰ <https://ihmecovid19storage.blob.core.windows.net/archive/2020-03-30/ihme-covid19.zip>

21 ²¹ *Id.*

22 ²² <https://ihmecovid19storage.blob.core.windows.net/archive/2020-04-01/ihme-covid19.zip>

23 ²³ *Id.*

24 ²⁴ *Id.*

25 ²⁵ <https://ihmecovid19storage.blob.core.windows.net/archive/2020-04-05/ihme-covid19.zip>

26 ²⁶ *Id.*

27 ²⁷ <http://www.healthdata.org/covid/data-downloads>

1 55. The May 4 IHME model predicted between 1068 and 1304 Washington state
2 deaths due to COVID-19, with a mean estimate of 1160 deaths.²⁸

3 56. The May 8 IHME model predicted between 1070 and 1189 Washington state deaths
4 due to COVID-19, with a mean estimate of 1120 deaths.²⁹

5 57. The May 8 IHME model predicted no shortage of hospital beds or ICE beds.³⁰

6 **OTHER RELEVANT HOSPITAL RESOURCES**

7 58. On March 30, 2020, the United States Army began assembling a 250-bed field
8 hospital at CenturyLink Field in Seattle, to make additional hospital capacity available for the
9 expected surge in required hospital beds.³¹

10 59. That facility became ready to receive patients on or about April 5, 2020.³²

11 60. On April 8, 2020, without having received a single patient, the facility was
12 disassembled and returned to the Army.³³

13 61. In late March or early April, the state procured 1,000 hospital beds and over 900
14 ventilators to assist hospitals responding to the COVID-19 emergency.³⁴

15 62. In late March or early April, the state leased the former Astria Regional Medical
16 Center in Yakima to serve as a 250-bed field hospital if a need arose in Central Washington.³⁵

17 **GOVERNOR INSLEE’S PROCLAMATIONS**

18 63. On February 29, 2020, Governor Jay Inslee issued Proclamation 20-05.³⁶

20 ²⁸ <https://ihmecovid19storage.blob.core.windows.net/archive/2020-05-04/ihme-covid19.zip>

21 ²⁹ <https://ihmecovid19storage.blob.core.windows.net/latest/ihme-covid19.zip> (visited May 10, 2020)

22 ³⁰ *Id.*

23 ³¹ <https://www.kuow.org/stories/washington-state-to-return-centurylink-field-hospital-to-feds>

24 ³² *Id.*

25 ³³ *Id.*

26 ³⁴ *Id.*

27 ³⁵ *Id.*

28 ³⁶ <https://www.governor.wa.gov/sites/default/files/proclamations/20-05%20Coronavirus%20%28final%29.pdf>

64. Proclamation 20-05 stated that the worldwide outbreak of COVID-19 was a “public disaster that affects life, health, property or the public peace.”³⁷

65. Proclamation 20-05 a State of Emergency existed in all counties in the state of Washington and directed the implementation of the plans and procedures contained in the Washington State Comprehensive Emergency Management Plan.³⁸

66. Governor Inslee based his declaration on Chapters 38.08, 38.52, and 43.06 RCW.³⁹

67. Proclamation 20-05 activated the organized militia of Washington State.⁴⁰

68. On March 23, 2020, Governor Inslee issued Proclamation 20-25, amending Proclamation 20-25 and entitled “Stay Home – Stay Healthy.” A copy may be found at <https://www.governor.wa.gov/sites/default/files/proclamations/20-25%20Coronavirus%20Stay%20Safe-Stay%20Healthy%20%28tmp%29%20%28002%29.pdf>

69. Proclamation 20-25 stated that “models predict that many hospitals in Washington State will reach capacity or become overwhelmed with COVID-19 patients within the next several weeks unless we substantially slow down the spread of COVID-19 throughout the state.”

70. No existing statute exists to address the potential problem of hospitals in Washington State reaching capacity or becoming overwhelmed with patients due to the rapid spread of a disease.

71. Proclamation 20-25 declared that “a State of Emergency continues to exist in all counties of Washington State.” Proclamation 20-25 imposed a “Stay Home – Stay Healthy Order throughout Washington State by prohibiting all people in Washington State from leaving their homes or participating in social, spiritual and recreational gatherings of any kind regardless of the

³⁷ *Id.*

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Id.*

1 number of participants, and all non-essential businesses in Washington State from conducting
2 business, within the limitations provided herein.”⁴¹

3 72. Proclamation 20-25 prohibited a list of activities “under the provisions of RCW
4 43.06.220(1)(h),” and provided that “Violators of this of this order [sic] may be subject to criminal
5 penalties pursuant to RCW 43.06.220(5).”⁴²

6 73. On April 2, 2020, Governor Inslee issued Proclamation 20-25.1, “Extending Stay
7 Home—Stay Healthy to May 4, 2020.”⁴³

8 74. Proclamation 20-25.1 stated that COVID-19 “has broadly spread throughout
9 Washington State and is a significant health risk to all of our people, especially members of our
10 most vulnerable populations.”⁴⁴

11 75. Proclamation 20-25.1 stated that there were at least 5,984 cases of COVID-19 in
12 Washington State with 247 associated deaths, and “models predict that many hospitals in
13 Washington State will reach capacity or become overwhelmed within the next few weeks unless
14 we significantly slow its spread throughout the state.”⁴⁵

15 76. Proclamation 20-25.1 also stated that “a large surge in the number of serious
16 COVID-19 infections will compromise the ability of our health care system to deliver necessary
17 health care services.”⁴⁶

18 77. Proclamation 20-25.1 stated that “a State of Emergency continues to exist in all
19 counties of Washington State,” under the authority of Chapters 38.08, 38.52 and 43.06 RCW.⁴⁷

22 ⁴¹ *Id.*

23 ⁴² *Id.*

24 ⁴³ [https://www.governor.wa.gov/sites/default/files/20-25.1%20-%20COVID-19%20-%20Stay%20Home%2C%20Stay%20Healthy%20Extension%20\(tmp\).pdf](https://www.governor.wa.gov/sites/default/files/20-25.1%20-%20COVID-19%20-%20Stay%20Home%2C%20Stay%20Healthy%20Extension%20(tmp).pdf)

25 ⁴⁴ *Id.*

26 ⁴⁵ *Id.*

27 ⁴⁶ *Id.*

⁴⁷ *Id.*

78. Proclamation 20-25.1 extended the provisions of Proclamation 20-25 “in full force and effect,” until 11:59 pm on May 4, 2020.⁴⁸

79. When Proclamation 20-25.1 was issued, the most recent IHME models predicted that hospitalizations would exceed available capacity in the state.⁴⁹

80. On May 4, 2020 Governor Inslee issued Proclamation 20-25.3, entitled “Adjusting and Extending Stay Home—Stay Healthy to May 31, 2020.”⁵⁰

81. Proclamation 20-25.3 states that “health professionals and epidemiological modeling experts predict that we have passed the peak of the progression [of the spread of the virus] in the state,” but that “modelers agree that fully relaxing social distancing measures will result in a sharp increase in the number of cases.”⁵¹

82. Proclamation 20-25.3 relaxes some of the restrictions imposed by previous Proclamations.⁵²

83. Proclamation 20-25.3 states that “the worldwide COVID-19 pandemic and its progression in Washington State continue to threaten the life and health of our people as well as the economy of Washington State, and remain a public disaster affecting life, health, property or the public peace . . .”⁵³

84. Proclamation 20-25.3 states that under Chapters 38.08, 38.52 and 43.06 RCW “a State of Emergency continues to exist in all counties of Washington State, that Proclamation 20-05 and all amendments thereto remain in effect as otherwise amended . . .”⁵⁴

⁴⁸ *Id.*

⁴⁹ <https://ihmecovid19storage.blob.core.windows.net/archive/2020-04-01/ihme-covid19.zip>

⁵⁰ <https://www.governor.wa.gov/sites/default/files/20-25.3%20-%20COVID-19%20Stay%20Home%20Stay%20Healthy%20-%20Reopening%20%28tmp%29.pdf>

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.*

85. Proclamation 20-25.3 states that “Violators of this order may be subject to criminal penalties pursuant to RCW 43.06.220(5). Further, if people fail to comply with the required social distancing while engaging in the phased modifications of the mandatory social distancing requirements, I may be forced to reinstate the prohibitions established in earlier proclamations.”⁵⁵

86. Proclamation 20-25.3 does not assert that any model predicts that any hospital in Washington state is in any danger of reaching capacity or becoming overwhelmed.⁵⁶

87. Proclamation 20-25.3 does not assert that any model predicts that the hospital system in Washington state is in any danger of reaching capacity or becoming overwhelmed.⁵⁷

88. No model predicts that any individual hospital, nor the statewide hospital system in Washington state is at danger of reaching capacity or being overwhelmed.

89. No model predicts that, if and when the Whitman County Health Department implements its pandemic flu preparedness and response plan in lieu of the Orders contained in Proclamation 20-25.3, the hospital system of Whitman County or the state of Washington will be in any danger of reaching capacity or becoming overwhelmed.

PANDEMIC FLU PREPAREDNESS

90. Chapter 70.26 RCW, “PANDEMIC INFLUENZA PREPAREDNESS,” addresses the response of state and local government to the outbreak of a novel virus that causes acute respiratory distress, spreads rapidly, and has the potential of killing as many as 5,000 people in Washington.

91. COVID-19 a novel virus that causes acute respiratory distress, spreads rapidly, and has been predicted to have the potential of killing as many as 3,239 people in Washington.⁵⁸

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ <https://ihmecovid19storage.blob.core.windows.net/archive/2020-03-30/ihme-covid19.zip>

92. COVID-19 has killed under 1,000 people in Washington (931 as of 8:40pm May 10, 2020).⁵⁹

93. COVID-19 is now predicted to kill a total of 1,189 people in Washington, or 248 more people in the indeterminate future than it has now killed in Washington.⁶⁰

94. The threat posed by COVID-19 is well within the parameters of the plans established by the state and county health departments pursuant to Chapter 70.26 RCW.

CONDITIONS IN WHITMAN COUNTY

95. As of May 10, 2020, there have been 15 confirmed cases of COVID-19 in Whitman County.⁶¹

96. As of May 10, 2020, there have been zero deaths due to COVID-19 in Whitman County.⁶²

97. There is no shortage of available hospital facilities to deal with foreseeable cases of COVID-19 in Whitman County.⁶³

98. There is no public disorder, energy emergency or riot in Whitman County.

99. The “public disaster” described in Proclamation 20-05 and subsequent iterations of that proclamation, namely the threat that hospital facilities will be overwhelmed and that needed medical care will be unavailable, no longer exists, at least in Whitman County.

100. Such “public disaster” will not come into existence if Proclamation 20-25.3 is lifted and the county’s 70.26 RCW pandemic preparedness plan is implemented under the direction of the Whitman County Health Department.

⁵⁹ <https://www.doh.wa.gov/Emergencies/NovelCoronavirusOutbreak2020COVID19/DataDashboard> (last visited at 8:40 pm May 10, 2020).

⁶⁰ <https://ihmecovid19storage.blob.core.windows.net/latest/ihme-covid19.zip> (last visited at 8:40 pm May 10, 2020).

⁶¹ <https://www.doh.wa.gov/Emergencies/NovelCoronavirusOutbreak2020COVID19/DataDashboard>

⁶² *Id.*

⁶³ *Id.*; *supra* n. 60, 61.

101. The enforcement of Proclamations 20-05, 20-25, 20-25.1 and 20-25.3 have resulted in grave damage to the economic well-being of citizens in Whitman County.

V. CAUSES OF ACTION

First Cause of Action: Declaratory Judgment

102. The allegations of the previous paragraphs are incorporated as if fully set forth herein.

103. Chapter 70.26 RCW addresses the potential for a “pandemic influenza” that could result in as many as five thousand deaths in Washington.

104. COVID-19 is within the definition of a “pandemic influenza,” which is “a new virus [that] appears in the human population, causes serious illness, and then spreads easily from person to person.” RCW 70.26.010.

105. None of the current projections for the ultimate number of deaths expected to result from COVID-19 predict more than a quarter of the number of deaths anticipated by RCW 70.26.010(3).

106. No prior projection for the ultimate number of deaths expected to result from COVID-19 predicted more than 5,000 deaths, below that anticipated by RCW 70.26.010(3).

107. RCW 43.06.010(12) authorizes the Governor, “after finding that a public disorder, disaster, energy emergency, or riot exists within this state or any part thereof which affects life, health, property, or the public peace, proclaim a state of emergency in the area affected, and the powers granted the governor during a state of emergency shall be effective only within the area described in the proclamation.”

108. The only justification for declaring a state of emergency based on COVID-19 was when it appeared that the sudden spread of COVID-19 could overwhelm the hospital and other health care resources available to provide medical care to COVID-19 victims.

109. Because Chapter 70.26 RCW anticipates the potential for an influenza pandemic and prescribes the means to respond to such a pandemic, the appearance of a novel virus such as

1 COVID-19 does not by itself constitute a “disaster” justifying the Proclamation of a state of
2 emergency.

3 110. No current model projecting the spread of COVID-19 anticipates that hospital and
4 other health care resources available to treat COVID-19 patients will be overwhelmed.

5 111. RCW 43.06.210 states that the Governor “must terminate said state of emergency
6 proclamation when order has been restored to the area affected.”

7 112. There is no threat to public order in Whitman County.

8 113. The health care resources available in Whitman County have been reduced because
9 of the prohibition on providing non-emergency health care.

10 114. Employees of health care facilities and providers in Whitman County have been told
11 that their wages will be reduced and their employment may end as a result of the inability of health
12 care providers to earn income.⁶⁴

13 115. The state of emergency declared by Governor Inslee because of COVID-19 is no
14 longer justified in Whitman County.

15 116. The plaintiff is entitled to a declaratory judgment that the restrictions imposed by
16 Governor Inslee’s Proclamations are no longer enforceable.

17 **Second Cause of Action: Injunctive Relief**

18 117. The allegations of the previous paragraphs are incorporated as if fully set forth
19 herein.

20 118. Governor Inslee’s proclamation declaring a state of emergency throughout all
21 counties in Washington was based on the potential for hospital and other health care resources to
22 be overwhelmed by a “surge” of COVID-19 cases that would exceed the capacity of existing
23 resources to handle.

24
25
26
27 ⁶⁴ <https://pullmanradio.com/pullman-regional-hospital-cuts-employee-pay-by-25-to-deal-with-drop-in-revenue-from-coronavirus-response-state-mandates/>

119. Now that there is no model from any recognized public health authority projecting the potential for hospital and other health care resources to be overwhelmed, RCW 43.06.210 requires Governor Inslee to terminate the state of emergency proclamation “when order has been restored in the area affected.”

120. Plaintiff has no adequate remedy at law for a continuation of the COVID-19 Proclamations beyond the time when they are justified.

121. Plaintiff is entitled to an injunction ordering Governor Inslee to terminate the COVID-19 Proclamations declaring a state of emergency in Whitman County.

122. Plaintiff is entitled to an injunction requiring Governing Inslee not to enforce the COVID-19 Proclamations in Whitman County.

Third Cause of Action: Declaratory Relief

123. The allegations of the previous paragraphs are incorporated as if fully set forth herein.

124. To whatever extent Chapter 43.06 RCW is not subject to judicial review as to the facts constituting an emergency, it is unconstitutional under at least Wash. Const. Art. II Sec. 1.

Fourth Cause of Action: Declaratory Relief

125. The allegations of the previous paragraphs are incorporated as if fully set forth herein.

126. To whatever extent Chapter 43.06 RCW allows the governor to proclaim an emergency to alter, override, or supersede existing statutes that govern the fact situation identified as an emergency, it is unconstitutional under at least Wash. Const. Art. II Sec. 1.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for the following relief:

1. For a declaratory judgment that Proclamation 20-08, Proclamation 20-09, and Proclamation 20-09.1 do not apply to Whitman County.

2. For injunctive relief requiring Governor Inslee to terminate any current order declaring a state of emergency in Whitman County.
3. For a Declaration that Chapter 43.06 RCW is unconstitutional.
4. For an award of Plaintiffs' costs of this suit, including attorney's fees.
5. For such other and further relief as this Court deems just and proper.

///

///

May 15, 2020.

ARD LAW GROUP PLLC

By: 

Joel B. Ard, WSBA # 40104

P.O. Box 11633

Bainbridge Island, WA 98110

(206) 701-9243

Joel@Ard.law

Attorneys for Plaintiffs

ALBRECHT LAW PLLC

By: 

David K. DeWolf, WSBA #10875

421 W. Riverside Ave., Ste. 614

Spokane, WA 99201

(509) 495-1246

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE


I certify under penalty of perjury under the laws of the United States of America that on May 15, 2020, I served the foregoing COMPLAINT in *Akesson v. Inslee*, together with a MOTION FOR TEMPORARY RESTRAINING ORDER, DECLARATION OF AKESSON IN SUPPORT OF THE MOTION, and PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW, all via email per agreement between the parties, on the following:

Kathryn Leathers, Kathryn.leathers@gov.wa.gov

Jeffrey Even, Jeffrey.even@atg.wa.gov

ARD LAW GROUP PLLC

By



Joel B. Ard, WSBA # 40104
P.O. Box 11633
Bainbridge Island, WA 98110
(206) 701-9243
Joel@Ard.law
Attorneys for Plaintiffs

Exhibit B

☒ EXPEDITE☐ No hearing set☐ Hearing is set

Date: _____

Time: _____

Judge: _____

STATE OF WASHINGTON
CHELAN COUNTY SUPERIOR COURT

JOSE LUIS CUEVAS, MARIA ADRIANA CUEVAS, CHAD SANGSTER, TRAVIS HORNSBY, RACHELLE JOHNSON, TRAVIS HOFSTETTER, PATRICK ARMSTRONG, LINDA HERALD, MICHELLE MCCORMICK, MARIO JOHNSON, JACKLYN JOHNSON, MEGAN JOHNSON, NORRIS WILLIAMS, CARY CONDOTTA, GREGG SMITH, HEATHER CARLSON, MATT FLUEGGE, JEFF GUENTZEL, JOSH HAMILTON, KENT McMULLIN, LARRY KING, MARK STODDARD, SHIRLEY STODDARD, WAYNE LORANGER, STEPHEN FREEMAN, JEFFREY KURPUIS, ADAM JAMES, JOSH MCPHERSON, PUUOKAALA PAUL COCKETT KNELL, KEVIN SMITH, SHON SMITH, CHRISTINA HORNER, HEIDI FORCHEMER, BLAINE JOHNSON, DUANE MARKER, MARCY COLLINS, JIM WALKER, DENNIS CARINO, JESSE RAINS, CHRISTOPHER DAE QUINN, DOUG BIANCHI, SANDRA ARELLENO, MEGAN SKERLONG, CALEB WEBER, JOHN DIVIS, AND DAVID QUICK,

Plaintiffs,

v.

STATE OF WASHINGTON, AND JAY INSLEE, IN HIS OFFICIAL CAPACITY AS GOVERNOR,

Defendants.

COMPLAINT FOR INJUNCTIVE AND
DECLARATORY RELIEF

1 Plaintiffs allege as follows:

2 **I. PRELIMINARY STATEMENT**

3 1. COVID-19 is a novel virus that can cause serious illness and can spread easily from
4 person to person.

5 2. Chapter 72.06 RCW provides direction for how to prepare for and respond to a
6 “novel virus” such as COVID-19. It places responsibility for doing so at the local level.

7 3. Now that it is clear that COVID-19 will not overwhelm hospital and other health
8 care resources in Chelan County, there is no longer a “disaster” or any other emergency justifying
9 the issuance of orders pursuant to RCW 43.06.220.

10 **II. JURISDICTION AND VENUE**

11 4. This Court has jurisdiction over the subject matter of this lawsuit.

12 5. Jose Luis Cuevas is a resident of Chelan County. He and the other Plaintiffs seek
13 declaratory and injunctive relief to prevent further personal injury and property damage.

14 6. Cuevas and other plaintiffs residing in Chelan County have a claim against the State
15 of Washington.

16 7. Governor Jay Inslee claims to act as an agent of the State of Washington in
17 restricting the Plaintiffs’ business and personal activities.

18 8. Venue is therefore proper pursuant to RCWA 4.92.010(1).

19 9. There is no emergency justifying Governor Inslee’s invocation of authority under
20 RCW 43.06.210.

21 10. The Governor’s orders restricting Plaintiffs’ ability to conduct business and engage
22 in personal activities are not made in virtue of his office.

23 11. The Governor’s orders restricting Plaintiffs’ ability to conduct business and engage
24 in personal activities are made under color of his office.

25 12. Governor Inslee and the State of Washington have a duty to each plaintiff to act in
26 accordance with law.

13. Governor Inslee and the State of Washington have breached their duty to each plaintiff to act in accordance with law.

14. Defendants' acts in breach of that duty have occurred in Chelan County, at least in the form of illegal orders to business owners to cease lawful operation of businesses.

15. Defendants' acts in breach of their duties have directly caused harm to each plaintiff.

16. Chelan County plaintiffs have been harmed by those breaches of duty in Chelan County.

17. The cause of action alleged in this complaint, or some part thereof, arose in Chelan County.

18. Specifically, the Governor's actions and the actions of the State of Washington, as alleged herein, have caused personal injury and property damage in Chelan County.

19. Plaintiffs further allege that the Governor and the State of Washington have acted in Chelan County to enforce unlawful orders.

20. Specifically, the Governor and the State of Washington has threatened one or more of the plaintiffs with deprivation of liquor or other business licenses necessary to conduct their business.

21. Venue is therefore proper in Chelan County.

III. PARTIES

The Chelan County Plaintiffs

A. Jose Luis Cuevas

22. Jose Luis Cuevas is a resident of Chelan County, Washington.

23. Mr. Cuevas owns an insurance business; his wife owns a beauty salon and they own a building on Wenatchee Ave., which they lease.

24. His household income has been reduced by more than eighty percent as his wife has not worked since the stay at home order was put in place and lost 100% of her income.

1 25. Mr. Cuevas' insurance business requires that he go door to door in order to sell
2 insurance. He has not been able to do so, causing his business income to be reduced 100%.

3 26. Mr. Cuevas and his wife have not been able to pay any business expenses or
4 mortgage on the building they own due to the lack of income.

5 27. Mr. Cuevas and his wife have not been able to lease their building because of the
6 economy suffering.

7 28. Mr. Cuevas and his family go to church every Sunday; however, they have been
8 unable to attend and celebrate our religious beliefs as they customarily do due to the closure of our
9 church.

10 29. His extended families normally get together every Sunday as a family and yet have
11 not been able to do so because of the Proclamations.

12 30. Mr. Cuevas is used to seeing his mother on a daily basis. Now, he has only seen her
13 two times and only from a distance for a few short minutes.

14 31. Mr. Cuevas thereby has been harmed and is still being harmed by the Proclamation.

15 **B. Maria Adriana Cuevas**

16 32. Ms. Cuevas is a resident of Chelan County, Washington.

17 33. Ms. Cuevas owns a small business, Adis Salon.

18 34. When the stay at home order went into effect, Ms. Cuevas lost the ability to earn a
19 living completely. Her family household income has decreased significantly due to her earnings
20 being more than fifty percent of the earnings of her household.

21 35. Ms. Cuevas is the owner of the building where she conducts business. Her business
22 uses the first half and she rents out the second half. She has not been able to lease the second half
23 of the building because of the standstill of the economy.

24 36. Still, she has outstanding utility bills and mortgage for the business due to being
25 unable to open.

26 37. Ms. Cuevas' family is very religious and attends church every Sunday. They are no
27 longer able to due to the proclamation.

38. Ms. Cuevas is unable to see extended family.

39. Ms. Cuevas no longer has the options of where to shop for necessities for her family.

40. Ms. Cuevas thereby has been harmed and is still being harmed by the Proclamation.

C. Chad Sangster

41. Mr. Sangster is a resident of Chelan County, Washington.

42. Mr. Sangster is a small business owner, of Sangster Motors Inc.

43. Mr. Sangster's business is down 70%+ plus in the last 2 months, creating tremendous professional, personal, mental, and emotional stress.

44. With each regulation added for compliance to the shut-down his business practices are forced to comply. What customers do come in often turn around and leave rather than adhere to the intrusive regulations and infringements of private information.

45. Long term planning, forecasting, and projections so essential for a viable business have become almost impossible.

46. The situation is critical. It is absolutely imperative Mr. Sangster reopen immediately. His current trajectory is financially unsustainable. His cash liquidity is tenable at best and current sales trajectories dire. He simply can't continue business at this pace. Unless he reopens immediately, his family business and the 50 households it supports will be drastically, negatively, and irreparably damaged. He is out of time.

47. Mr. Sangster thereby has been harmed and is still being harmed by the Proclamation.

D. Travis Hornsby

48. Mr. Hornsby is a resident of Chelan County, Washington.

49. Mr. Hornsby is the President and Project Manager for the local chapter of Evergreen Mountain Bike Alliance, a state-wide non-profit with 7 chapters.

50. Due to the shutdown, EMBA has lost down \$30,000 in lost funds due to cancelled fundraiser events.

1 51. Mr. Hornsby's budget is based on volunteer work. Without the ability to use
2 volunteers he have \$30,000 of work scheduled that cannot be done, significantly impeding
3 EMBA's ability to serve both the local and tourist outdoor recreation community.

4 52. Mr. Hornsby is also a small business owner, of Blue Palm Frozen yogurt.

5 53. Mr. Hornsby has lost over \$75,000 in sales revenue during the Proclamations. This
6 revenue would have helped support 6 different families that work for Blue Palm and has been
7 permanently lost.

8 54. As a self-service frozen yogurt shop Mr. Hornsby's business is built on a pleasing
9 aesthetic experience. Without indoor seating, movies, couches, live music, and self-service, he
10 cannot draw patrons and is severely hampered in serving the ones who come.

11 55. Mr. Hornsby is currently unable to pay bills, including rent and business loans, and
12 has lost significant personal income.

13 56. Mr. Hornsby was forced to lay off 6 staff (most of whom were students and ineligible
14 for unemployment, thus negatively impacting their ability to pay school bills, etc.) with uncertainty
15 of when he can rehire.

16 57. Mr. Hornsby's business is seasonal, with small profit margins per unit of sale.

17 58. If Mr. Hornsby does not make money in the summer, his business will not make it
18 through the winter.

19 59. His business is out of options and on the razor's edge of survival.

20 60. If he cannot reopen immediately, he will be forced to permanently close.

21 61. Mr. Hornsby thereby has been harmed and is still being harmed by the
22 Proclamation.

23 **E. Rachelle Johnson**

24 62. Ms. Johnson is a resident of Chelan County, Washington.

25 63. Ms. Johnson is a small business owner of The Inner Circle Gym and mother to 3
26 children.

64. Ms. Johnson shut her business down after three months of operations, lost her evening job, and her child's school shut down all in the same day.

65. Ms. Johnson has yet to receive a penny of unemployment.

66. Ms. Johnson sees irrevocable changes in the lives of her gym members, like depression, panic attacks, unhealthy coping, and elderly losing their independence.

67. Ms. Johnson's job that supported her business is not running at capacity, nor will for the foreseeable future, leaving her with very little in the way of taking care of herself or her children who are suffering academically, as well as emotionally.

68. Ms. Johnson has taken out a \$150,000 business loan, signed a \$250,000 5-year lease, and must now pay on both while staring at an empty building with no business.

69. Membership in her gym is down 25% and falling by the day.

70. Ms. Johnson is in the middle of a divorce and has become the sole bread winner for her children. Her personal and business bankruptcies are almost inevitable.

71. Ms. Johnson must open her gym immediately for her business to survive.

72. Ms. Johnson thereby has been harmed and is still being harmed by the Proclamation.

F. Travis Hofstetter

73. Mr. Hofstetter is a resident of Chelan County, Washington.

74. Mr. Hofstetter currently has 8 construction jobs that were affected by shut downs per Governor Inslee's order. Total gross revenue of these projects equals \$4,955,000. On any given month, his business generates \$500,000 to \$1,000,000 in gross revenues per month. This is revenue he cannot get back because the time has been lost.

75. Mr. Hofstetter have 6 new homes to build with a gross revenue of \$3,750,000 that will be jeopardized if there is no relief. These are jobs that he cannot start right now due to current restrictions.

76. Mr. Hofstetter lost 1 job completely since he was not able to start the project. The estimated gross revenue lost was \$500,000. He cannot get this back.

1 77. Mr. Hofstetter will have to lay off 3 employees in the next 3 months if this shut
2 down is not lifted and he is unable to continue work.

3 78. With no ability to replace the homes (or revenue) that are currently under
4 construction, his business and livelihood are in jeopardy.

5 79. Mr. Hofstetter thereby has been harmed and is still being harmed by the
6 Proclamation.

7 **G. Patrick Armstrong**

8 80. Mr. Armstrong is a resident of Chelan County, Washington.

9 81. Mr. Armstrong owns Pat Armstrong Ford.

10 82. His company employs 50 people, many of whom are young families with children.

11 83. The Proclamations and State enforcement in Chelan County make it impossible to
12 plan for the future, in a business with huge capital costs in addition to payroll needs that help
13 maintain a well trained workforce.

14 84. Absent prompt relief from the Proclamations and State enforcement of them, Mr.
15 Ford will be unable to preserve his workforce, which can take its valuable skills and experience to
16 states that are not blocking businesses from operating in safe and higher capacity manners.

17 85. The continuing uncertainty from living under emergency proclamations that
18 change day to day and week to week make it impossible to engage in meaningful business planning,
19 such that the effect of the Proclamations and enforcement will last for weeks and months after they
20 are lifted.

21 86. Every day of delay in restoring rule of statutory law lengthen the recovery for Mr.
22 Ford's business.

23 **H. Linda Herald**

24 87. Ms. Herald is a resident of Chelan County, Washington.

25 88. Ms. Herald had to lay off approximately 45 employees due to the Covid-19
26 pandemic.

89. Ms. Herald's business, KCSY FM radio, is down by 50% and if the Stay at Home Order stays in effect much longer, she and her husband will lose the business.

90. This would create an extreme financial hardship for her family, and also her employees who are dependent on their paychecks.

91. As an elected official, Ms. Herald is very concerned about the economic impact this is having on her community. Many of local businesses will not recover and will be forced to file bankruptcy. Ultimately, due to the loss of tax dollars, this will have a huge impact on our ability to provide services for our citizens.

92. Ms. Herald thereby has been harmed and is still being harmed by the Proclamation.

I. Michelle McCormick

93. Ms. McCormick is a resident of Chelan County, Washington.

94. Ms. McCormick is the leader of a non-profit that serves over 700 children in the Wenatchee Valley each year.

95. She has been working 45-60 hours per week from home trying to run the organization "virtually." The weight of it all keeps her from sleeping at night.

96. Ms. McCormick had to cancel 2 summer camps and postpone her largest money-making performance of the year, putting her non-profit \$70,000 in the red by year-end.

97. Just this week she was forced to make the difficult decision to close her doors, go dormant and stop the bleed in hopes of having some funds left to restart at some point.

98. As a group dependent on gatherings (youth classes, rehearsals and shows) her 4 employees and 11 contractors are out of work until Ms. McCormick is able to get groups of children together again.

99. In addition to the financial loss from gatherings, Ms. McCormick has lost her annual sponsors because the surrounding businesses are all struggling as well.

100. This equates to \$30,000 loss for the year.

101. Ms. McCormick is completely exhausted from trying to maintain what little bit of income she had, but now those programs have ended as has any cash flow.

1 102. Ms. McCormick will be filing for unemployment this week along with the rest of
2 her team.

3 103. Ms. McCormick thereby has been harmed and is still being harmed by the
4 Proclamation.

5 **J. Mario Clint Johnson**

6 104. Mr. Johnson is a resident of Chelan County, Washington.

7 105. Mr. Johnson and his wife have two sons, one of which was born with severe
8 developmental delays. Consequently, he does not walk or talk and does not learn in the same way
9 other young people do. He relies 100% on assistance from Mr. Johnson, his wife, and his caregivers
10 and thrives on the human social and physical interaction he receives from others, including
11 teachers and classmates.

12 106. Governor Inslee's order to keep schools closed not only ended his school year
13 prematurely, it has also denied him real social and physical interaction with his teachers, peers and
14 therapists. Such interaction is not possible through "Distance Learning" and is an important
15 component of his ability to live a healthy and happy life.

16 107. As a manager in the business of excavation, Mr. Johnson is required to implement
17 and enforce unnecessary construction jobsite practices aimed primarily at vertical and indoor
18 construction that present safety hazards to employees.

19 108. For example, employees wearing masks while performing difficult manual labor are
20 more susceptible to respiratory fatigue and heat stroke. This requirement will persist under phase
21 2 guidelines and will pose even greater risk to employees under summer conditions. With outdoor
22 construction activities, normal social distancing measures are easily obtainable with very few
23 exceptions. A practice such as this creates more risk than it protects and should be at the discretion
24 of the individual.

25 109. Mr. Johnson thereby has been harmed and is still being harmed by the Proclamation.

26 **K. Jacklyn Dawn Johnson**

27 110. Ms. Johnson is a resident of Chelan County, Washington.

111. Ms. Johnson is a mother of a special needs child who thrives on social experiences, and the imposed limitations are negatively affecting his well-being.

112. Ms. Johnson's son's quality of life is being diminished, because he has been unable to attend his last few months of school before graduating, and he is unable to participate in volunteering at the local humane society or attend numerous birthday parties

113. Because of his condition, Ms. Johnson's son cannot speak, but must live daily knowing how much this frustrates him.

114. Ms. Johnson value these things – faith, family, friends and the freedom to engage in actions that add to these.

115. The Governor's edicts have put unreasonable constraints upon Ms. Johnson's pursuit of a creating a fulfilling and meaningful life for herself and her children.

116. Not being allowed to gather, to share experiences, to be able to obtain or give emotional/physical support causes Ms. Johnson excruciating emotional pain.

117. Ms. Johnson thereby has been harmed and is still being harmed by the Proclamation.

L. Megan Johnson

118. Ms. Johnson is a resident of Chelan County, Washington.

119. Ms. Johnson must to homeschool her daughter, while working a full-time, essential job outside of the home. There is not enough time in the day to be able to do both. Her job and her daughter's education are suffering as a result.

120. Ms. Johnson suffers from anxiety and depression and has a very hard time getting her prescription so she can function every day, and be the mom, wife, daughter, employee, and sister she needs to be.

121. As a result, with her daily routine so out of order, Ms. Johnson has had to increase her dosage of medication. Her mental health is being harmed as a result of these restrictions.

122. Ms. Johnson thereby has been harmed and is still being harmed by the Proclamation.

M. Norris Williams

123. Mr. Williams is a resident of Chelan County, Washington.

124. Mr. Williams has been unable to see his chiropractor or massage therapist to help him with the constant pain he lives with.

125. Because of this, the shooting pain in his right arm, neck and lower back has become almost unbearable in the last two months to the point he cannot sleep or function normally throughout his days.

126. Mr. Williams has greatly increased his need for over the counter pain medicine as he has been unable to get to any doctor appointments due to the restrictions of Governor Inslee.

127. Mr. Williams' International and US leadership coaching and training work has suffered greatly as Mr. Williams has been unable to travel to meet with clients.

128. This loss of work has severely diminished his income.

129. Mr. Williams and his wife have been unable to spend time with his nine grandchildren spread across the state of Washington. This loss of time with them has been very grievous to him and his family. It is time he can never get back.

130. Mr. Williams and his wife attend church, as well as weekly meetings with community groups. They have been unable to attend these meetings and witness unnecessary and unwarranted fear and anxiety increase in their family.

131. Mr. Williams thereby has been harmed and is still being harmed by the Proclamation.

N. Cary Condotta

132. Mr. Condatta is a resident of Chelan County, Washington.

133. Mr. Condatta income has been substantially reduced making it difficult for him to make house payments and pay debts. His clients who he consults with are suffering as well.

134. Mr. Condatta lost one client and several more may soon cease to exist. These relationships took years to build and are now being destroyed.

135. Mr. Condatta needs to be in the gym at least three days a week to maintain his current weight. He has been unable to do so and his physical health is deteriorating.

136. Mr. Condatta thereby has been harmed and is still being harmed by the Proclamation.

O. Gregg Smith

137. Mr. Smith is a resident of Chelan County, Washington.

138. Mr. Smith is a husband, father, employer and member of a local church and has suffered much harm due to Governor Inslee's shutdown of our state and region.

139. Mr. Smith's four school-aged children have not been able to attend classes or social activities, including his oldest son who is missing high school graduation ceremonies.

140. Mr. Smith's family and has not been able to attend the local church on Sunday or meet mid-week for in-home Bible study.

141. Mr. Smith's small business has struggled to stay profitable due to the many restrictions from the Governor and the lack of cooperation from state agencies that are needed for construction businesses to continue.

142. Mr. Smith's business will not survive much longer unless these restrictions are lifted immediately; it is possible that his business cannot survive for even another week.

143. Mr. Smith thereby has been harmed and is still being harmed by the Proclamation.

P. Heather Carlson

144. Ms. Carlson is a resident of Chelan County, Washington.

145. Ms. Carlson is a homeschooling mother of 6 children, including 3 biological and 3 adopted out of foster care.

146. Ms. Carlson is a licensed foster parent and trauma care trainer.

147. Ms. Carlson's children have no longer been able to attend their weekly classes through an education cooperative, nor any extracurricular activities.

1 148. Ms. Carlson's son and his classmates missed out on being able to present a mock
 2 trial case to a judge and jury and he is currently missing out on attending his driver's ed classes in
 3 person, getting his permit, and beginning to practice driving.

4 149. Ms. Carlson and her husband were unable to host an annual in-person conference
 5 for professionals and people working with children impacted by trauma.

6 150. Ms. Carlson is unable to provide follow-up trauma care training that she has
 7 provided in the past to adoption agencies and was prepared to provide to those interested within
 8 the community, including teachers, foster/adoptive parents, social workers, CASAs, churches,
 9 and healthcare workers.

10 151. The increase in drug abuse, suicide, alcoholism, domestic violence, and overall
 11 stress due to the stay at home order makes the training Ms. Carlson provides imperative yet
 12 impossible thus creating more untreated trauma in the community, and work for her and everyone
 13 else trying to help bring about healing in the lives of those greatly impacted by trauma.

14 152. Ms. Carlson thereby has been harmed and is still being harmed by the Proclamation.

15 **Q. Matt Fluegge**

16 153. Mr. Fluegge is a resident of Chelan County, Washington.

17 154. Mr. Fluegge is a father of four boys, a husband, and owns a general dentistry in East
 18 Wenatchee, WA.

19 155. Due to Washington state's "Stay Home Stay Healthy" order, his business has been
 20 put in financial jeopardy.

21 156. Mr. Fluegge's patients have suffered and not received necessary but "non-
 22 emergency" dental treatment.

23 157. Mr. Fluegge's children have lost roughly half a years' worth of education, which
 24 can never be substituted with Zoom meetings and impromptu assignments. This has been
 25 devastating to his family.

26 158. Mr. Fluegge thereby has been harmed and is still being harmed by the Proclamation.
 27

R. Jeff Guentzel

159. Mr. Guentzel is a resident of Chelan County, Washington.

160. Mr. Guentzel owns a fitness gym and has been compelled to lay off six of his seven employees.

161. Mr. Guentzel and his wife are losing over \$10,000 per month. He cannot continue to pay his mortgage, his business rent, his insurance, his utilities and his taxes.

162. He cannot attend church and be spiritually encouraged.

163. Mr. Guentzel cannot receive normal care from his doctor and dentist.

164. Mr. Guentzel thereby has been harmed and is still being harmed by the Proclamation.

S. Josh Hamilton

165. Mr. Hamilton is a resident of Chelan County, Washington.

166. Mr. Hamilton's daughter, who has juvenile idiopathic arthritis requiring regular physical assessment by her rheumatologist at Seattle Children's Hospital, is unable to be evaluated for her condition. This has caused frustration and worry for her well-being.

167. Mr. Hamilton has elderly parents who he is unable to help whether it be install a microwave or mow their lawn.

168. Mr. Hamilton's elderly parents need assistance from him but are now isolated, fearful to go to the doctor and denied a hug from their grandchildren.

169. Mr. Hamilton has been denied the basic right to assemble, pray and connect with people on Sunday and throughout the week, which has a life altering spiritual impact upon him and his family.

170. Mr. Hamilton is regularly experiencing ostracization, mental distress, isolation, and loss of purpose.

171. Mr. Hamilton thereby has been harmed and is still being harmed by the Proclamation.

T. Kent McMullen

172. Mr. McMullen is a resident of Chelan County, Washington.

173. Mr. McMullen's household income has been negatively impacted due to his wife being furloughed.

174. Mr. McMullen has not been able to see, or even help take care of his five grandchildren, help which his son and daughter depend on. These are moments he will never get back.

175. Mr. McMullen had to lay off his 90-year old father's caregiver due to the Stay-At-Home order, which has now made it difficult for him to maintain his father's level of care.

176. Additionally, his father has ongoing health issues and has been under the regular care of doctors monthly, but has not been able to see them during this time.

177. Mr. McMullen is concerned that his father's diabetes and eye issues have worsened as a result of this.

178. Mr. McMullen has been unable to perform his daily pastoral ministry of being with people who are hurting emotionally, mentally, psychologically, and spiritually.

179. Mr. McMullen has not been able to perform weddings or funerals or visit the sick in the hospital. The extending pain on the people he loves and serves will last well into the future.

180. Mr. McMullen thereby has been harmed and is still being harmed by the Proclamation.

U. Larry King

181. Mr. King is a resident of Chelan County, Washington.

182. Mr. King owns commercial real estate, which has been severely impacted as tenants have been unable to pay rent. However, his loan payment and taxes have all been due without relief during this time, which has caused great financial strain.

183. Mr. King has been unable to attend church service and wasn't even able to attend his grandson's baptism.

1 184. Mr. King's wife's scheduled surgery was cancelled due to COVID-19 and has not
 2 yet been rescheduled. She has endured endless pain since then, which has in turn caused him great
 3 anguish.

4 185. Mr. King is employed as a pilot with Alaska Airlines. His industry has been
 5 decimated by the shutdown, resulting in greatly reduced personal income and a very tenuous
 6 future.

7 186. Mr. King is very distressed he will be forced to retire early to salvage what he can
 8 from his pension.

9 187. Mr. King is unable to see or care for his 84-year-old mother, who lives in Seattle
 10 and is battling a variety of health issues.

11 188. Mr. King is unable to visit his pregnant daughter, who also lives in Seattle.

12 189. Mr. King and his wife are missing moments that he can never recapture.

13 190. Mr. King thereby has been harmed and is still being harmed by the Proclamation.

14 **V. Mark Stoddard**

15 191. Mr. Stoddard is a resident of Chelan County, Washington.

16 192. Mr. Stoddard is a 62-year-old retired resident of Leavenworth, WA.

17 193. As a son, husband, father and grandfather Mr. Stoddard has experienced harm from
 18 the COVID-19 restrictions enacted by the State of Washington.

19 194. Mr. Stoddard has experienced financial harm due to loss of income from vacation
 20 rental property, but the most significant impacts are of an emotional, mental and physical nature.

21 195. Mr. Stoddard's mental and emotional health are being harmed due to numerous
 22 prohibitions.

23 196. Mr. Stoddard is prohibited from visiting his 88-year-old father, who could pass
 24 before Mr. Stoddard can see him.

25 197. Mr. Stoddard is prohibited from visiting his son, daughter-in-law and 3-year-old
 26 granddaughter. He will never get those missed opportunities back.

1 198. Mr. Stoddard is prohibited from hosting weekly community church group (12-15
2 people) in his home and from having weekly meals with neighbors.

3 199. Mr. Stoddard is prohibited from gathering for weekly church services.

4 200. Mr. Stoddard's physical and mental health are also being harmed as he is prohibited
5 from seeking medical/dental attention for hip and back issues, as well as preventative care. And,
6 he is prohibited from participating in exercise activities – guided river rafting trips, mountain bike
7 trips, and pickleball.

8 201. Mr. Stoddard thereby has been harmed and is still being harmed by the
9 Proclamation.

10 **W. Shirley Stoddard**

11 202. Ms. Stoddard is a resident of Chelan County, Washington.

12 203. Ms. Stoddard is a 65-year-old retired resident of Leavenworth, WA. She is a female
13 minority, daughter, wife, mother and grandmother who has experienced harm from the COVID-
14 19 restrictions enacted by the State of Washington.

15 204. Ms. Stoddard has experienced financial harm due to loss of income from vacation
16 rental property, but the most significant impacts are of an emotional, mental and physical nature.

17 205. Her mental and emotional health are being harmed due to numerous prohibitions.
18 She is prohibited from visiting her 88-year-old father, who could pass before she can see him.

19 206. Ms. Stoddard is prohibited from visiting her son, daughter-in-law and 3-year-old
20 granddaughter, and will never get those missed opportunities back.

21 207. Ms. Stoddard is prohibited from hosting weekly community church group (12-15
22 people) in her home or having weekly meals with neighbors.

23 208. Ms. Stoddard is prohibited from gathering for weekly church services.

24 209. Ms. Stoddard's physical and mental health are also being harmed as she is
25 prohibited from seeking medical/dental attention for issues and preventative care, and prohibited
26 from participating in exercise activities – guided river rafting trips, mountain bike trips, pickleball,
27 and yoga.

1 210. Ms. Stoddard thereby has been harmed and is still being harmed by the
2 Proclamation.

3 **X. Wayne Loranger**

4 211. Mr. Loranger is a resident of Chelan County, Washington.

5 212. Mr. Loranger is a retired individual currently ineligible for Social Security benefits.

6 213. Mr. Loranger relies on income from rental properties. Yet 50% of his tenants are in
7 arrears on their rent due to COVID-19.

8 214. Mr. Loranger is ineligible for any relief from the State or Federal Governments and
9 received no stimulus money.

10 215. Mr. Loranger is barred from even getting new tenants.

11 216. Mr. Loranger thereby has been harmed and is still being harmed by the
12 Proclamation.

13 **Y. Stephen Freeman**

14 217. Mr. Freeman is a resident of Chelan County, Washington.

15 218. Mr. Freeman is a small business owner of a local restaurant.

16 219. Against lost wages and the 82% loss of normal daily sales, Mr. Freeman has “To
17 Go” and on-line sales, which provides only 18% of the normal sales.

18 220. With capital and overhead expenses undiminished, Mr. Freeman experiences an
19 unsustainable negative cash Flow.

20 221. Upon Phase 2 of the Governor’s 4-Phase Plan, even at 50% capacity, Mr. Freeman
21 will be unable to bring back the entire staff or make ends meet.

22 222. In order for Mr. Freeman to re-open and even breakeven, he needs a minimum of
23 80% seating capacity to mitigate the outflow.

24 223. Mr. Freeman is financially harmed by current restrictions that have made his once
25 profitable business unprofitable and have hampered his ability to fully recover.

26 224. Mr. Freeman thereby has been harmed and is still being harmed by the
27 Proclamation.

Z. Jeffrey Kurpuis

225. Mr. Kurpuis is a resident of Chelan County, Washington.

226. Mr. Kurpuis' freedom to assemble and worship with his church family, in any form and manner, including his home group, to have fellowship, learn together and pray for each other has been outright banned.

227. Mr. Kurpuis' freedom to travel where he wishes and associate with whom he wishes, has been banned, including his parents, siblings and children who live in their own homes, effectively making the "Stay Home, Stay Safe" order, into a very real form of house arrest.

228. Mr. Kurpuis is a small business owner. The onerous requirements for business operations have placed undue, unreasonable burdens on operating in a self-determined, reasonably safe manner.

229. Additionally, these new safety requirements invade privacy, and are not being applied equally to all businesses, but imposed on his and not other similar businesses.

230. Mr. Kurpuis thereby has been harmed and is still being harmed by the Proclamation.

AA. Adam James

231. Mr. James is a resident of Chelan County, Washington.

232. Mr. James' wife was furloughed from her job.

233. Mr. James' children have been unable to see their friends.

234. Mr. James' 14-year old son didn't even realize he was "saying goodbye" to many of his friends as his 8th grade year was cut short. He'll never go back to that school.

235. Mr. James' 8-year old son, who is in need of special services due to an auditory processing disorder, has suffered from the lack of those services. Mr. James' wife has been in tears as she has spent hours trying to work with him, hoping to keep him from falling further behind.

236. Mr. James' children have been kept from their aging grandparents.

237. Mr. James has been robbed of freedoms and traditions and been subjected to fear and anxiety as a result of the prolonged order.

238. Mr. James has been cut off from the people he loves and serves as a pastor.

1 239. Mr. James thereby has been harmed and is still being harmed by the Proclamation.

2 **BB. Josh McPherson**

3 240. Mr. McPherson is a resident of Chelan County.

4 241. Mr. McPherson is a husband, father of four children, and Lead Pastor of Grace City
5 Church.

6 242. As a husband, Mr. McPherson has experienced increased stress from his wife's
7 limited medical access. In February, she had heart surgery and due to the quarantine was unable to
8 attend her follow up appointments.

9 243. As a father, the stress of change and impact to Mr. McPherson's family has come
10 in many forms. His elder daughter has spina bifida, but due to travel restrictions and hospital
11 closure, her bowel regiment training was canceled, prolonging her dependence on enemas, and
12 putting off her continence independence as a teenager. Her horse hippo therapy was canceled,
13 missing critical developmental experience.

14 244. Mr. McPherson's next two children had countless events canceled, sporting events
15 cut short, and unique musical and cultural experiences they will never get back. As a father, this
16 weighs heavy on him.

17 245. As an individual, Mr. McPherson had a previously scheduled spinal injection to
18 relieve chronic and severe back pain. This was canceled and he has been forced to live with
19 significant pain that could have otherwise been relieved.

20 246. As a pastor, the mental, emotional, and spiritual stress of not being able to meet
21 with his flock, care for his church family, and speak to them face to face every week has grown
22 increasingly heavy. It is having a real and material impact on his psyche.

23 247. As a pastor, the burden of watching depression spike, porn use spike, addictions
24 spike, suicide spike, unemployment spike, and the overall morale of his community slide into
25 further darkness has been almost unbearable.

26 248. Mr. McPherson feels helpless and cut off from the very people he is called to serve.
27

249. As lead visionary pastor, the focus of Mr. McPherson's leadership has been to finish a 42,000sf, \$16M dollar facility. The shuttering of the project has caused significant financial stress, disrupting a complex construction schedule and supply chain, and extending the move in date by 5 months. The cost of construction has increased significantly. This is a significant burden that presents a real and present threat to the viability of the church family.

250. The impact of the prolonged lockdown is changing the future of Mr. McPherson's profession and how he will spend the balance of his life's work.

251. Mr. McPherson will live with its effects long after Covid-19 is gone. He must reopen immediately.

252. Mr. McPherson thereby has been harmed and is still being harmed by the Proclamation

CC. Puuokaala Paul Cockett Knell

253. Mr. Knell is a resident of Chelan County, Washington.

254. Mr. Knell's family of 5 has been dramatically impacted by the orders of our state officials to shut down as a response to the Covid-19 virus.

255. Mr. Knell receives disheartening messages while at work nearly daily from his wife who has been carrying the brunt of the at-home schooling of two boys (10 and 9yrs old) due to the closure of the private school they attend while his 4-year old daughter is essentially ignored.

256. Both sons have expressed clear symptoms of depression as they are isolated from friends and family.

257. Mr. Knell is concerned about the long term impact to his kids.

258. Mr. Knell is also concerned that the school his children attend and where his wife works could have to close its doors in the fall as a result of families unable to pay tuition due to this prolonged closure.

259. In Mr. Knell's community there is no similar alternative for the type of education, leaving our family without a schooling solution and reduced household income.

1 260. Mr. Knell is unable to visit his last grandparent in hospice, who could pass any day.
 2 Her daily activities now are reduced to staring out a window or watching subpar television to pass
 3 the time.

4 **DD. Kevin Smith**

5 261. Mr. Smith is a resident of Chelan County, Washington.

6 262. Mr. Smith owns the Windmill, a restaurant in Wenatchee.

7 263. On May 27, 2020, Mr. Smith opened the Windmill for business.

8 264. Mr. Smith not only received numerous patrons, he also booked tables for a week in
 9 advance, promptly upon announcing he was taking reservations.

10 265. Within hours of opening, Mr. Smith received a call from an agent of defendant State
 11 of Washington, specifically, an employee in the Yakima Enforcement Office of the Washington
 12 State Liquor and Cannabis Board.

13 266. That employee informed Mr. Smith that if he did not immediately close his doors,
 14 and not reopen them until authorized to do so by subsequent amendment to Proclamation 20-25,
 15 the Liquor and Cannabis Board would send an employee from the Wenatchee Field office in Chelan
 16 County to the Windmill, seize Mr. Smith's liquor license, and ensure that Mr. Smith was banned
 17 for life from ever holding a liquor license in Washington State.

18 267. Mr. Smith complied with that order, despite believing it illegal.

19 268. Mr. Smith lost revenue from that day, as well as a week's worth of reservations he
 20 had to cancel.

21 269. Mr. Smith has been and is being harmed by actions of Jay Inslee in his official
 22 capacity of the Governor of Washington.

23 270. Mr. Smith has been and is being harmed by actions of the State of Washington,
 24 undertaken in Yakima County and in Chelan County, the location of Mr. Smith upon receipt of the
 25 threat of enforcement.

26 **EE. Shon Smith**

27 271. Mr. Smith is a resident of Chelan County, Washington.

272. Mr. Smith is a local small business owner.

273. Mr. Smith's business, his sole income source, has suffered and is suffering due to the current restrictions in place caused by COVID-19.

274. His \$3 million a year business supported a payroll of more than \$1.4 million.

275. Mr. Smith has been forced to lay off all 63 of his employees, who have families, mortgages, rents, diapers, food and the list goes on. Their lives are in danger.

276. The future of his business is in jeopardy.

277. He has had to take 2 loans against the business that he painstakingly built with 7-days a week work for the last 24 years.

278. The term on the SBA loan that he had to borrow due to COVID-19 shutdown puts the payoff on his 80th birthday.

279. These new loans may not even save the business.

280. Mr. Smith is in grave danger of losing his life's work.

Douglas County Plaintiffs

FF. Christina Horner

281. Ms. Horner is a resident of Chelan County.

282. With a business partner, Ms. Horner owns The Old Post Office Saloon in Leavenworth, and had started the process of opening a second establishment in Cashmere.

283. Due to the Proclamations, she has had to lay off all employees, yet continue paying commercial property leases that are not bringing in income and halt work on the second business, despite having paid for permits and licensing.

284. The uncertainty and financial hardship resulting from the Proclamations and State enforcement threaten the future viability of the business.

GG. Heidi Forchemer

285. Ms. Forchemer is a resident of Chelan County, Washington.

286. Ms. Forchemer is the owner of three restaurants in Leavenworth, Washington.

1 287. The Proclamations and State enforcement of restriction on restaurant operations
2 has drastically harmed all her businesses, and she has been forced to incur massive debt simply to
3 preserve the businesses.

4 288. Absent prompt relief from the Proclamations and State enforcement, the survival
5 of her businesses is at grave risk.

6 **HH. Blaine Johnson**

7 289. Mr. Johnson is a resident of Chelan County.

8 290. Mr. Johnson is the sales manager at a car dealership.

9 291. The constantly changing predictions of future and regulations makes doing business
10 practically impossible

11 292. Purchasing cars to stock in this market is financially dangerous because no one
12 knows how potential customers will be allowed to be addressed from week to week.

13 293. Further, banks will not finance to people on unemployment which is a growing
14 fraction of the community.

15 294. The Proclamations and State enforcement of them is thereby preventing Mr.
16 Johnson from providing for his children.

17 **II. Duane Marker**

18 295. Mr. Marker is a resident of Chelan County, Washington.

19 296. Mr. Marker owns Doghouse Motorsports.

20 297. When the quarantine was originally enforced, Mr. Marker's business was deemed
21 an essential business and allowed to remain partially open.

22 298. Nonetheless, the impact on his business was immediate, but not yet desperate.

23 299. However, the weight of caring for his 11 employees is increasingly more stressful.

24 300. With rules changing press conference to press conference, it is barely possible to
25 know if the business can continue and the employees will continue to have jobs from week to week
26 and month to month.

27 301. The business is seasonal in nature and runs on small margins.

302. Every sale generated during this critical selling window is essential to the business's survival.

303. Mr. Marker is now well into the critical season, and the ongoing quarantine and accompanying regulations and restrictions are significantly constraining the business.

304. Without the critical revenue normally generated in this season, the result is quite simple: his business will not survive the coming fall, and will fail.

JJ. Marcy Collins

305. Ms. Collins is a resident of Chelan County, Washington.

306. Ms. Collins owns and operates Collins Fashions, her primary source of income.

307. The business had a healthy bank account until the past two months of shutdown.

308. The business accrued losses of around \$150,000, which continue to grow.

309. Ms. Collins has sizable payables due to numerous vendors and taxes due in June.

310. When she realized that if she did not open the store, by May 31 her bank account would be empty.

311. With safety measures in place she opened for curbside and single person shopping appointments.

312. She had in place vastly more safety and security measures than are present at large retailers that the state allows to operate, such as Home Depot, Target, and other Fortune 500 businesses which have never been closed down.

313. Collins Fashion also had designated "essential" items for sale such as masks, hand sanitizer, food products, soaps, attire and comfort shoes for essential workers, etc.

314. She opened the store with safety measures May 15.

315. She did so in order to be able to pay her five employees that rely on their income from Collins.

316. She feels personally responsible for employee and customer safety

1 317. Collins' employees' jobs are her responsibility and if she cannot open ASAP, like
 2 Target, Home Depot, and every other chain of a Fortune 500 company that the state has deemed
 3 "essential," she will not have the funds to pay their next paycheck.

4 318. After opening, on May 27, 2020 a person who, on information and belief, was an
 5 agent of defendant State of Washington entered her store and inquired about her operations.

6 319. An hour later Collins received an email from MIL WA Essential Business.

7 320. The email stated that Collins was in violation of Proclamation 20-25.

8 321. The letter specifically threatened that the violation the Proclamation could result
 9 in loss of a business license, fines, Consumer Protection Action suits, or criminal penalties.

10 322. As a result Collins' business closed again, unlike comparable businesses that the
 11 State prefers to allow to operate, because they are listed on major stock exchanges, for example.

12 323. The complete lack of predictability associated with the various "Phases" of the so-
 13 called emergency preclude any rational business planning. Collins cannot know from day-to-day
 14 what rules will govern her business, much less know what rules the State plans to impose in a
 15 month.

16 324. She needs to have the assurance of future rules in place to be able to place thousands
 17 of dollars of orders for merchandise to arrive in August through November 2020

18 325. With no stability in governing rules, Collins cannot see a possible future for her
 19 business.

20 Douglas County Plaintiffs

21 **A. Jim Walker**

22 326. Mr. Walker is a resident of Douglas County, Washington.

23 327. Mr. Walker lives, works, and employees people in Douglas County.

24 328. Mr. Walker is the owner of Lone Pine Fruit & Espresso, established in 2000 and
 25 Lone Pine Orchard, established in 1998.

26 329. Due to the Stay at Home order and the nature of the business, he has been unable
 27 to conduct business at its fullest.

1 330. This restriction is causing devastating financial hardship on not only to Mr. Walker,
2 but also to his 13 employees and their families.

3 331. Mr. Walker and his employees depend on the influx of travelers on Highway 97 to
4 support the business and their jobs. He was unable to catch the Memorial Day Weekend business,
5 his busiest weekend of the year, and any delay in being able to reopen will be catastrophic to the
6 financial stability of the business.

7 332. If more weeks, or even days, pass under these reduced conditions, Mr. Walker's
8 business of twenty years will not survive.

9 333. Mr. Walker thereby has been harmed and is still being harmed by the Proclamation.

10 **B. Dennis Carino**

11 334. Mr. Carino is a resident of Douglas County, Washington.

12 335. Mr. Carino is a small business owner. Due to the "Stay at Home" order and the
13 nature of his restaurant business, he have been unable to conduct profitable business resulting in
14 devastating financial harm.

15 336. Mr. Carino was unable to open for dining-in during the Memorial Day weekend,
16 which is one of the busiest weekends of the year for his restaurant, and the financial harm he has
17 suffered and will suffer will be catastrophic and will likely cause the failure of his business.

18 337. Mr. Carino thereby has been harmed and is still being harmed by the Proclamation.

19 **C. Jesse Rains**

20 338. Mr. Rains is a resident of Douglas County, Washington.

21 339. Mr. Rains owns a local small business, Joe's East Sports Bar & Grill.

22 340. Due to the "Stay at Home" order and the nature of the business, Mr. Rains has
23 been unable to continue to conduct business.

24 341. The financial harm has been devastating as Mr. Rains has already missed St.
25 Patrick's Day, which is the busiest day for his business, as well as the local Apple Blossom Festival.

342. Mr. Rains was unable to open the Memorial Day weekend business, which is one of the busiest weekends of the year for the hospitality industry, and if he is unable to reopen the financial harm will be catastrophic and likely to cause the failure of his business..

343. Mr. Rains thereby has been harmed and is still being harmed by the Proclamation.

D. Christopher Dae Quinn

344. Mr. Quinn is a resident of Douglas County, Washington.

345. Mr. Quinn owns property in Douglas County, the city of East Wenatchee.

346. Mr. Quinn has commercial tenants unable to pay rent and portions of their expenses for extended periods of time as their businesses are required to be closed due to State orders.

347. This has caused these businesses to lay off or furlough hundreds of employees and has dropped his rental income to zero on these properties.

348. Mr. Quinn's real estate expenses meanwhile, such as taxes, maintenance, debt service, and insurance, continue to eat away at reserves.

349. Mr. Quinn's and his wife's salaries have been slashed by 40%. Being self-employed, they are not eligible for unemployment benefits, or Paycheck Protection Program funding of any sort.

350. Mr. Quinn is unable to attend weekly church services and worship with fellow believers. His spiritual life is actively being harmed, and in this difficult and emotional time he lacks the normal support he would receive from fellow church members.

351. Mr. Quinn thereby has been harmed and is still being harmed by the Proclamation.

E. Doug Bianchi

352. Mr. Bianchi is a resident of Douglas County, Washington.

353. Mr. Bianchi's business revenues are down at least 50% resulting in severe loss of personal income, inability to pay the mortgage on his family farm, and inability to properly maintain his agricultural crop.

354. Mr. Bianchi was forced to lay-off two employees.

355. Mr. Bianchi thereby has been harmed and is still being harmed by the Proclamation.

F. Sandra Arelleno

356. Ms. Arelleno is a resident of Douglas County.

357. Ms. Arelleno is a hair dresser and a personal trainer at a local gym.

358. Ms. Arelleno is a single mom to three boys and lives with her parents because she is on unemployment.

359. Prior to the Proclamations, Ms. Arelleno was looking for a home to buy for her kids but now has to stay with her parents because she doesn't have a job.

360. Unemployment payments are not enough for her to provide for her children.

361. She can only hope that the salon she worked at will be able to open again so she can work, but that is uncertain because no one knows how long salons will have to stay closed, or what conditions will be imposed if they are allowed to reopen.

362. Further, the gym she trained at is closed and she can't count on that income for a long time.

G. Megan Skerlong

363. Ms. Skerlong is a resident of Douglas County, Washington.

364. Ms. Skerlong operates Tousled Salon in Chelan County.

365. Due to the Proclamations, and State threats to revoke her licenses if she refuses to comply, Tousled Salon has seen no business for two and a half months.

366. Tousled Salon, like most salons, specializes in cleanliness and sanitization protocol, and implemented such protocols far before any State mandates.

367. Ms. Skerlong is educated and licensed in how to prevent spread of disease and cross-contamination. She and her business are far more careful regarding safety than businesses which are deemed "essential" and allowed to be open, like marijuana sellers.

368. The ongoing additional mandates from the State imposed on Tousled and Ms. Skerlong continue to damage her financial future.

H. Caleb Weber

369. Mr. Weber is a resident of Douglas County, Washington.

1 370. Mr. Weber operates a startup business, Fetch PRM, that sells software to veterinary
2 practices.

3 371. The Proclamations have barred his new business from meeting, despite that other
4 businesses deemed “essential” by the State can have employees meet and do business.

5 372. The ongoing bans by the State in enforcing the Proclamations also forbid him and
6 his team from visiting veterinary practices, preventing him from selling the product they have
7 developed.

8 373. Continued enforcement by the State of the Proclamations will cause his business to
9 fail.

10 **I. John Divis**

11 374. Dr. Divis is a resident of Douglas County, Washington.

12 375. Dr. Divis has a Doctorate of Dental Surgery.

13 376. Dr. Divis owns a private dentistry practice.

14 377. Despite financial relief efforts by government officials, Dr. Divis’ practice has
15 experienced a significant loss of income, which has produced significant financial strain.

16 378. Dr. Divis expect a second wave of economic effects on the practice as people who
17 have lost their businesses discontinue their regular dental care, negatively impacting their dental
18 health as well.

19 379. Dr. Divis thereby has been harmed and is still being harmed by the Proclamation.

20 Defendants

21 380. The State of Washington acts through its Governor, Jay Inslee.

22 381. Jay Inslee is the Governor of the State of Washington.

23 **J. David Quick**

24 382. Mr. Quick is a resident of Douglas County.

25 383. Mr. Quick is the managing member of Badger Mountain Brewing, LLC at 1 Orondo
26 Ave., Wenatchee in Chelan County.

27 384. The business consists of a dine in restaurant and a production brewery.

385. Mr. Quick had to furlough 4 full time and 8 part time employees as well as
discontinue the services of several of vendors due to the Proclamations.

386. His fixed expenses for the business whether open or not are approximately \$8000
per month.

387. The business may never recover from being forced to close for the last 2 1/2 months
and any greater period of closure makes recovery that much more unlikely.

388. The Proclamations various proposed limitations on seating for restaurants in the
various stages also guarantees further losses.

389. Busy periods cover for losses normally incurred during slower times; the
Proclamations likely ensure that will not happen.

390. Violations of the Proclamations are enforced by the State of Washington by seizure
and forfeiture of the required liquor license.

391. Mr. Quick invested most of his life savings invested in the business, and at the age
of 62 will never again be able accumulate the resources to make that size of an investment.

392. This closure is not just life changing but retirement destroying.

IV. FACTUAL ALLEGATIONS

A. Conditions in Chelan County

393. As of May 21, 2020, there have been 202 confirmed cases of COVID-19 in Chelan
County.¹

394. As of May 21, 2020, there have been 6 deaths due to COVID-19 in Chelan County.²
At least five of the six deaths were people at least 80 years old.³

395. The cases have been easily handled by the existing health system infrastructure,
which is now operating at below capacity.

¹ <https://www.doh.wa.gov/Emergencies/NovelCoronavirusOutbreak2020COVID19/DataDashboard>

² *Id.*

³ <https://www.ncwlife.com/all-five-coronavirus-deaths-in-chelan-county-have-been-people-80-or-older/>

1 396. Few if any healthcare workers have become infected, and the dreaded scenario in
2 which the healthcare system was itself crippled by a workforce that had become carriers of COVID-
3 19 never materialized.

4 397. There is no public disorder, energy emergency or riot in Chelan County.

5 398. The chief official of the Chelan–Douglas Health District, Dr. Malcolm Butler,
6 asserts the District “is prepared for and capable of dealing with the threat to public health currently
7 posed by COVID-19, as well as the additional threat posed by a phased reopening of the economy.”

8 399. Dr. Butler also “do[es] not anticipate a shortage of hospital or other health care
9 resources to deal with the COVID-19 pandemic.”

10 400. The emergency response center established jointly by Chelan and Douglas
11 Counties to prevent the hospital system from being overrun in the event of a mass outbreak has
12 partially deactivated and transitioned into “Recovery Mode,” which is defined as a non emergency
13 situation.

14 401. The sheriff of Chelan County, Brian Burnett, has deemed the current circumstance
15 as “not . . . an emergency”, in contrast to others he has experienced in his professional career such
16 as wildfires or mudslides.

17 402. Sheriff Burnett, however, considers that although no civil unrest has emerged in
18 direct response to the pandemic or from overloading of the hospital system, it is substantially likely
19 to occur if the stay-at-home order and resultant social and economic paralysis persist.

20 403. Dr. Butler has joined other public officials in Chelan County in requesting the
21 Governor loosen the restrictions imposed by the Proclamations in Chelan County. The governor
22 rejected this request.

23 404. There is no shortage of available hospital facilities to deal with foreseeable cases of
24 COVID-19 in Chelan County.⁴

27 ⁴ *Id.*; *supra* n. 60, 61.

1 405. Such “public disaster” will not come into existence if Proclamation 20-25.3 is lifted
2 and the county’s 70.26 RCW pandemic preparedness plan is implemented under the direction of
3 the Chelan-Douglas Health District.

4 406. The enforcement of Proclamations 20-05, 20-25, 20-25.1 and 20-25.3 have resulted
5 in grave damage to the physical, emotional, educational, interpersonal, religious, and economic
6 well-being of citizens in Chelan County.

7 **B. Pandemic Flu Preparedness**

8 407. Chapter 70.26 RCW, “PANDEMIC INFLUENZA PREPAREDNESS,” addresses
9 the response of state and local government to the outbreak of a novel virus that causes acute
10 respiratory distress, spreads rapidly, and has the potential of killing as many as 5,000 people in
11 Washington.

12 408. COVID-19 a novel virus that causes acute respiratory distress, spreads rapidly, and
13 has been predicted to have the potential of killing as many as 3,239 people in Washington.⁵

14 409. COVID-19 has killed under 1,000 people in Washington (931 as of 8:40pm May 10,
15 2020).⁶

16 410. COVID-19 is now predicted to kill a total of 1,189 people in Washington, or 248
17 more people in the indeterminate future than it has now killed in Washington.⁷

18 411. The threat posed by COVID-19 is well within the parameters of the plans
19 established by the state and county health departments pursuant to Chapter 70.26 RCW.

20 **C. The Nature of COVID-19**

21 412. COVID-19 is caused by a virus.⁸

24 ⁵ <https://ihmecovid19storage.blob.core.windows.net/archive/2020-03-30/ihme-covid19.zip>

25 ⁶ <https://www.doh.wa.gov/Emergencies/NovelCoronavirusOutbreak2020COVID19/DataDashboard>
(last visited at 1:00 pm May 11, 2020).

26 ⁷ <https://ihmecovid19storage.blob.core.windows.net/latest/ihme-covid19.zip> (last visited at 8:40 pm
27 May 10, 2020).

⁸ <https://www.cdc.gov/coronavirus/2019-ncov/faq.html#Coronavirus-Disease-2019-Basics>

1 413. The COVID-19 virus first began to infect humans in 2019.⁹

2 414. The COVID-19 virus is a new virus within the meaning of RCW 70.26.010(1).

3 415. COVID-19 can cause serious illness.¹⁰

4 416. COVID-19 spreads easily from person to person.¹¹

5 417. Merriam-Webster defines “flu” as “1: influenza” and “2: any of several virus
6 diseases marked especially by respiratory or intestinal symptoms.”¹²

7 418. Merriam-Webster defines “influenza” as “1a : an acute, highly contagious,
8 respiratory disease caused by any of three orthomyxoviruses . . .” and “1b: any of various human
9 respiratory infections of undetermined cause —not used technically.”¹³

10 419. Merriam-Webster adds “Note: All types of influenza are commonly called “the
11 flu.”¹⁴

12 420. COVID-19 is a viral disease.¹⁵

13 421. The COVID-19 virus is a coronavirus.¹⁶

14 422. COVID-19 is marked especially by respiratory symptoms.¹⁷

15 423. COVID-19 is an acute, highly contagious respiratory disease.¹⁸

16 424. COVID-19 satisfies the common English definition of “flu” and “influenza” as
17 those words are used in RCW 70.26.010, whether or not the virus falls within the same scientific
18
19

20 ⁹ *Id.*

21 ¹⁰ *Id.*

22 ¹¹ *Id.*

23 ¹² <https://www.merriam-webster.com/dictionary/flu>

24 ¹³ <https://www.merriam-webster.com/dictionary/influenza>

25 ¹⁴ *Id.*

26 ¹⁵ *Id.*

27 ¹⁶ *See supra* note 1.

¹⁷ <https://www.cdc.gov/coronavirus/2019-ncov/faq.html#Symptoms-&-Testing>

¹⁸ https://wwwnc.cdc.gov/eid/article/26/7/20-0282_article

1 classification taxonomy of seasonal influenza, the Asian flu of 1957-58, the Hong Kong flu in 1968-
2 69, or the 2006 Avian or bird flu.

3 425. The first case of COVID-19 was confirmed in Snohomish County, Washington on
4 January 21, 2020.¹⁹

5 426. Prior to January 21, 2020 no case had been reported anywhere else in the United
6 States.

7 **D. The IHME COVID-19 Models**

8 427. The Institute for Health Metrics and Evaluation (IHME) is an independent global
9 health research center at the University of Washington.²⁰

10 428. IHME has modeled the likely course of COVID-19 in Washington state, including
11 predictions of cases, deaths, and use of health care resources, importantly including hospital beds,
12 intensive care unit beds, and invasive ventilators.²¹

13 429. IHME's first predictive model was issued on March 25, 2020.²²

14 430. IHME subsequently issued updated models on March 26, 2020; March 27, 2020;
15 March 29, 2020; March 30, 2020; March 31, 2020; April 1, 2020; April 5, 2020; April 7, 2020;
16 April 8, 2020; April 10, 2020; April 13, 2020; April 17, 2020; April 21, 2020; April 22, 2020; April
17 27, 2020; April 28, 2020; April 29, 2020; May 4, 2020; and May 8, 2020.²³

18 431. The March 25 IHME model and all subsequent IHME models are predicated on
19 various assumptions, including that Washington practiced "social distancing," shorthand for the
20 various mandates of the Proclamations.²⁴

23 ¹⁹ <https://www.snohd.org/495/COVID-19-General-Information>

24 ²⁰ <http://www.healthdata.org/about>

25 ²¹ <http://www.healthdata.org/covid>

26 ²² <http://www.healthdata.org/covid/data-downloads>

27 ²³ *Id.*

²⁴ *Id.*

1 432. The March 25 IHME model predicted between 312 and 2710 Washington State
2 deaths due to COVID-19, with a mean estimate of 1429 deaths.²⁵

3 433. The March 25 IHME model also predicted that by April 14, 2020, at worst
4 Washington state could have a shortage of available hospital beds of as many as 97 beds that day,
5 increasing to an unmeetable need of over 635 beds by April 23, and declining thereafter until there
6 was no predicted shortage by May 3.²⁶

7 434. The March 30 IHME model predicted between 462 and 3,239 Washington state
8 deaths due to COVID-19, with a mean estimate of 1621 deaths.²⁷

9 435. The March 30 IHME model also predicted that by April 13, 2020, at worst
10 Washington state could have a shortage of available hospital beds of as many as 37 beds that day,
11 increasing to an unmeetable need of over 1270 beds by April 29, and declining thereafter until there
12 was no predicted shortage by May 16.²⁸

13 436. The April 1 IHME model predicted between 468 and 1636 Washington state deaths
14 due to COVID-19, with a mean estimate of 978 deaths.²⁹

15 437. The April 1 IHME model no longer predicted that Washington would face any
16 shortage of total hospital beds.³⁰

17 438. The April 1 IHME model did predict that, in a worst case scenario, Washington
18 would face a shortage of available ICE beds beginning March 30, 2020 of 23 beds, peaking with a
19 shortage on April 14 of 275 beds, and continuing through May 4, 2020.³¹

22 ²⁵ <https://ihmecovid19storage.blob.core.windows.net/archive/2020-03-25/ihme-covid19.zip>

23 ²⁶ *Id.*

24 ²⁷ <https://ihmecovid19storage.blob.core.windows.net/archive/2020-03-30/ihme-covid19.zip>

25 ²⁸ *Id.*

26 ²⁹ <https://ihmecovid19storage.blob.core.windows.net/archive/2020-04-01/ihme-covid19.zip>

27 ³⁰ *Id.*

³¹ *Id.*

439. The April 5 IHME model predicted between 557 and 741 Washington state deaths due to COVID-19, with a mean estimate of 632 deaths.³²

440. The April 5 IHME model no longer predicated a potential shortage of either hospital beds or ICU beds.³³

441. No subsequent IHME model has predicted a potential shortage of any needed hospital resource.³⁴

442. The May 4 IHME model predicted between 1068 and 1304 Washington state deaths due to COVID-19, with a mean estimate of 1160 deaths.³⁵

443. The May 8 IHME model predicted between 1070 and 1189 Washington state deaths due to COVID-19, with a mean estimate of 1120 deaths.³⁶

444. The May 8 IHME model predicted no shortage of hospital beds or ICE beds.³⁷

E. The Role of the Chelan-Douglas Health District

445. At the time the Original Complaint in this case was filed, Plaintiffs were led to believe that the Chelan-Douglas Health District was ready, willing, and able to assume responsibility for dealing with the COVID-19 crisis.

446. The Board of the Chelan-Douglas Health District will meet on Monday, June 1, 2020 to decide whether to become a party to this suit.

447. Plaintiffs predict that the Chelan-Douglas Health District will seek status in this case as an intervening party.

³² <https://ihmecovid19storage.blob.core.windows.net/archive/2020-04-05/ihme-covid19.zip>

³³ *Id.*

³⁴ <http://www.healthdata.org/covid/data-downloads>

³⁵ <https://ihmecovid19storage.blob.core.windows.net/archive/2020-05-04/ihme-covid19.zip>

³⁶ <https://ihmecovid19storage.blob.core.windows.net/latest/ihme-covid19.zip> (visited May 10, 2020)

³⁷ *Id.*

F. Other Relevant Hospital Resources

448. On March 30, 2020, the United States Army began assembling a 250-bed field hospital at CenturyLink Field in Seattle, to make additional hospital capacity available for the expected surge in required hospital beds.³⁸

449. That facility became ready to receive patients on or about April 5, 2020.³⁹

450. On April 8, 2020, without having received a single patient, the facility was disassembled and returned to the Army.⁴⁰

451. In late March or early April, the state procured 1,000 hospital beds and over 900 ventilators to assist hospitals responding to the COVID-19 emergency.⁴¹

452. In late March or early April, the state leased the former Astria Regional Medical Center in Yakima to serve as a 250-bed field hospital if a need arose in Central Washington.⁴²

G. Governor Inslee's Proclamations

453. On February 29, 2020, Governor Jay Inslee issued Proclamation 20-05.⁴³

454. Proclamation 20-05 stated that the worldwide outbreak of COVID-19 was a “public disaster that affects life, health, property or the public peace.”⁴⁴

455. Proclamation 20-05 a State of Emergency existed in all counties in the state of Washington and directed the implementation of the plans and procedures contained in the Washington State Comprehensive Emergency Management Plan.⁴⁵

³⁸ <https://www.kuow.org/stories/washington-state-to-return-centurylink-field-hospital-to-feds>

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

⁴³ <https://www.governor.wa.gov/sites/default/files/proclamations/20-05%20Coronavirus%20%28final%29.pdf>

⁴⁴ *Id.*

⁴⁵ *Id.*

1 456. Governor Inslee based his declaration on Chapters 38.08, 38.52, and 43.06 RCW.⁴⁶

2 457. Proclamation 20-05 activated the organized militia of Washington State.⁴⁷

3 458. On March 23, 2020, Governor Inslee issued Proclamation 20-25, amending
4 Proclamation 20-25 and entitled “Stay Home – Stay Healthy.” A copy may be found at
5 [https://www.governor.wa.gov/sites/default/files/proclamations/20-](https://www.governor.wa.gov/sites/default/files/proclamations/20-25%20Coronavirus%20Stay%20Safe-Stay%20Healthy%20%28tmp%29%20%28002%29.pdf)
6 [25%20Coronavirus%20Stay%20Safe-Stay%20Healthy%20%28tmp%29%20%28002%29.pdf](https://www.governor.wa.gov/sites/default/files/proclamations/20-25%20Coronavirus%20Stay%20Safe-Stay%20Healthy%20%28tmp%29%20%28002%29.pdf)

7 459. Proclamation 20-25 stated that “models predict that many hospitals in Washington
8 State will reach capacity or become overwhelmed with COVID-19 patients within the next several
9 weeks unless we substantially slow down the spread of COVID-19 throughout the state.”

10 460. No existing statute exists to address the potential problem of hospitals in
11 Washington State reaching capacity or becoming overwhelmed with patients due to the rapid
12 spread of a disease.

13 461. Proclamation 20-25 declared that “a State of Emergency continues to exist in all
14 counties of Washington State.” Proclamation 20-25 imposed a “Stay Home – Stay Healthy Order
15 throughout Washington State by prohibiting all people in Washington State from leaving their
16 homes or participating in social, spiritual and recreational gatherings of any kind regardless of the
17 number of participants, and all non-essential businesses in Washington State from conducting
18 business, within the limitations provided herein.”⁴⁸

19 462. Proclamation 20-25 prohibited a list of activities “under the provisions of RCW
20 43.06.220(1)(h),” and provided that “Violators of this of this order [sic] may be subject to criminal
21 penalties pursuant to RCW 43.06.220(5).”⁴⁹

25 ⁴⁶ *Id.*

26 ⁴⁷ *Id.*

27 ⁴⁸ *Id.*

⁴⁹ *Id.*

1 463. On April 2, 2020, Governor Inslee issued Proclamation 20-25.1, “Extending Stay
2 Home—Stay Healthy to May 4, 2020.”⁵⁰

3 464. Proclamation 20-25.1 stated that COVID-19 “has broadly spread throughout
4 Washington State and is a significant health risk to all of our people, especially members of our
5 most vulnerable populations.”⁵¹

6 465. Proclamation 20-25.1 stated that there were at least 5,984 cases of COVID-19 in
7 Washington State with 247 associated deaths, and “models predict that many hospitals in
8 Washington State will reach capacity or become overwhelmed within the next few weeks unless
9 we significantly slow its spread throughout the state.”⁵²

10 466. Proclamation 20-25.1 also stated that “a large surge in the number of serious
11 COVID-19 infections will compromise the ability of our health care system to deliver necessary
12 health care services.”⁵³

13 467. Proclamation 20-25.1 stated that “a State of Emergency continues to exist in all
14 counties of Washington State,” under the authority of Chapters 38.08, 38.52 and 43.06 RCW.⁵⁴

15 468. Proclamation 20-25.1 extended the provisions of Proclamation 20-25 “in full force
16 and effect,” until 11:59 pm on May 4, 2020.⁵⁵

17 469. When Proclamation 20-25.1 was issued, the most recent IHME models predicted
18 that hospitalizations would exceed available capacity in the state.⁵⁶

19
20
21
22 ⁵⁰ [https://www.governor.wa.gov/sites/default/files/20-25.1%20-%20COVID-19%20-%20Stay%20Home%2C%20Stay%20Healthy%20Extension%20\(tmp\).pdf](https://www.governor.wa.gov/sites/default/files/20-25.1%20-%20COVID-19%20-%20Stay%20Home%2C%20Stay%20Healthy%20Extension%20(tmp).pdf)

23 ⁵¹ *Id.*

24 ⁵² *Id.*

25 ⁵³ *Id.*

26 ⁵⁴ *Id.*

27 ⁵⁵ *Id.*

⁵⁶ <https://ihmecovid19storage.blob.core.windows.net/archive/2020-04-01/ihme-covid19.zip>

1 470. On May 4, 2020 Governor Inslee issued Proclamation 20-25.3, entitled “Adjusting
2 and Extending Stay Home—Stay Healthy to May 31, 2020.”⁵⁷

3 471. Proclamation 20-25.3 states that “health professionals and epidemiological
4 modeling experts predict that we have passed the peak of the progression [of the spread of the
5 virus] in the state,” but that “modelers agree that fully relaxing social distancing measures will
6 result in a sharp increase in the number of cases.”⁵⁸

7 472. Proclamation 20-25.3 relaxes some of the restrictions imposed by previous
8 Proclamations.⁵⁹

9 473. Proclamation 20-25.3 states that “the worldwide COVID-19 pandemic and its
10 progression in Washington State continue to threaten the life and health of our people as well as
11 the economy of Washington State, and remain a public disaster affecting life, health, property or
12 the public peace . . .”⁶⁰

13 474. Proclamation 20-25.3 states that under Chapters 38.08, 38.52 and 43.06 RCW “a
14 State of Emergency continues to exist in all counties of Washington State, that Proclamation 20-
15 05 and all amendments thereto remain in effect as otherwise amended . . .”⁶¹

16 475. Proclamation 20-25.3 states that “Violators of this order may be subject to criminal
17 penalties pursuant to RCW 43.06.220(5). Further, if people fail to comply with the required social
18 distancing while engaging in the phased modifications of the mandatory social distancing
19 requirements, I may be forced to reinstate the prohibitions established in earlier proclamations.”⁶²

20
21
22
23 ⁵⁷ <https://www.governor.wa.gov/sites/default/files/20-25.3%20-%20COVID-19%20Stay%20Home%20Stay%20Healthy%20-%20Reopening%20%28tmp%29.pdf>

24 ⁵⁸ *Id.*

25 ⁵⁹ *Id.*

26 ⁶⁰ *Id.*

27 ⁶¹ *Id.*

⁶² *Id.*

1 476. Proclamation 20-25.3 does not assert that any model predicts that any hospital in
2 Washington state is in any danger of reaching capacity or becoming overwhelmed.⁶³

3 477. Proclamation 20-25.3 does not assert that any model predicts that the hospital
4 system in Washington state is in any danger of reaching capacity or becoming overwhelmed.⁶⁴

5 478. No model predicts that any individual hospital, nor the statewide hospital system
6 in Washington state is at danger of reaching capacity or being overwhelmed.

7 479. No model predicts that, if and when the Chelan-Douglas Health District
8 implements its pandemic flu preparedness and response plan in lieu of the Orders contained in
9 Proclamation 20-25.3, the hospital system of Chelan County or the state of Washington will be in
10 any danger of reaching capacity or becoming overwhelmed.

11 V. CAUSES OF ACTION

12 A. First Cause of Action: Declaratory Judgment

13 480. The allegations of the previous paragraphs are incorporated as if fully set forth
14 herein.

15 481. Chapter 70.26 RCW addresses the potential for a “pandemic influenza” that could
16 result in as many as five thousand deaths in Washington.

17 482. COVID-19 is within the definition of a “pandemic influenza,” which is “a new
18 virus [that] appears in the human population, causes serious illness, and then spreads easily from
19 person to person.” RCW 70.26.010.

20 483. None of the current projections for the ultimate number of deaths expected to result
21 from COVID-19 predict more than a quarter of the number of deaths anticipated by RCW
22 70.26.010(3).

23 484. No prior projection for the ultimate number of deaths expected to result from
24 COVID-19 predicted more than 5,000 deaths, below that anticipated by RCW 70.26.010(3).

26 ⁶³ *Id.*

27 ⁶⁴ *Id.*

1 485. RCW 43.06.010(12) authorizes the Governor, “after finding that a public disorder,
2 disaster, energy emergency, or riot exists within this state or any part thereof which affects life,
3 health, property, or the public peace, proclaim a state of emergency in the area affected, and the
4 powers granted the governor during a state of emergency shall be effective only within the area
5 described in the proclamation.”

6 486. The only justification for declaring a state of emergency based on COVID-19 was
7 when it appeared that the sudden spread of COVID-19 could overwhelm the hospital and other
8 health care resources available to provide medical care to COVID-19 victims.

9 487. Because Chapter 70.26 RCW anticipates the potential for an influenza pandemic
10 and prescribes the means to respond to such a pandemic, the appearance of a novel virus such as
11 COVID-19 does not by itself constitute a “disaster” justifying the Proclamation of a state of
12 emergency.

13 488. No current model projecting the spread of COVID-19 anticipates that hospital and
14 other health care resources available to treat COVID-19 patients will be overwhelmed.

15 489. RCW 43.06.210 states that the Governor “must terminate said state of emergency
16 proclamation when order has been restored to the area affected.”

17 490. There is no threat to public order in Chelan and Douglas Counties.

18 491. The health care resources available in Chelan and Douglas Counties have been
19 reduced because of the prohibition on providing non-emergency health care.

20 492. Employees of health care facilities and providers serving Chelan and Douglas
21 Counties have been told that their wages will be reduced and their employment may end as a result
22 of the inability of health care providers to earn income.⁶⁵

23 493. The state of emergency declared by Governor Inslee because of COVID-19 is no
24 longer justified in Chelan and Douglas Counties.

25
26
27 ⁶⁵ https://www.wenatcheeworld.com/news/coronavirus/update-confluence-health-implements-salary-reductions-for-some-staff/article_ba3e7a36-7f68-11ea-94d5-bb7730a66883.html

1 494. The plaintiff is entitled to a declaratory judgment that the restrictions imposed by
2 Governor Inslee's Proclamations are no longer enforceable.

3 **B. Second Cause of Action: Injunctive Relief**

4 495. The allegations of the previous paragraphs are incorporated as if fully set forth
5 herein.

6 496. Governor Inslee's proclamation declaring a state of emergency throughout all
7 counties in Washington was based on the potential for hospital and other health care resources to
8 be overwhelmed by a "surge" of COVID-19 cases that would exceed the capacity of existing
9 resources to handle.

10 497. Now that there is no model from any recognized public health authority projecting
11 the potential for hospital and other health care resources to be overwhelmed, RCW 43.06.210
12 requires Governor Inslee to terminate the state of emergency proclamation "when order has been
13 restored in the area affected."

14 498. Plaintiff has no adequate remedy at law for a continuation of the COVID-19
15 Proclamations beyond the time when they are justified.

16 499. Plaintiff is entitled to an injunction ordering Governor Inslee to terminate the
17 COVID-19 Proclamations declaring a state of emergency in Chelan and Douglas Counties.

18 500. Plaintiff is entitled to an injunction requiring the State of Washington not to enforce
19 the COVID-19 Proclamations in Chelan and Douglas Counties.

20 **C. Third Cause of Action: Declaratory Relief**

21 501. The allegations of the previous paragraphs are incorporated as if fully set forth
22 herein.

23 502. To whatever extent Chapter 43.06 RCW is not subject to judicial review as to the
24 facts constituting an emergency, it denies Plaintiffs due process of law and is unconstitutional
25 under at least Wash. Const. Art. II Sec. 1.

D. Fourth Cause of Action: Declaratory Relief

503. The allegations of the previous paragraphs are incorporated as if fully set forth herein.

504. To whatever extent Chapter 43.06 RCW allows the governor to proclaim an emergency to alter, override, or supersede existing statutes that govern the fact situation identified as an emergency, it is unconstitutional under at least Wash. Const. Art. II Sec. 1.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for the following relief:

1. For a declaratory judgment that the Governor's Proclamations related to response to COVID-19 do not apply to Chelan and Douglas Counties.
2. For injunctive relief requiring Governor Inslee to terminate any current order declaring a state of emergency in Chelan and Douglas Counties.
3. For injunctive relief banning the State of Washington from enforcing any limitations on action pursuant to any current order declaring a state of emergency in Chelan and Douglas Counties.
4. For a Declaration that Chapter 43.06 RCW is unconstitutional.
5. For an award of Plaintiffs' costs of this suit, including attorney's fees.
6. For such other and further relief as this Court deems just and proper.

June 1, 2020.

ARD LAW GROUP PLLC

By: 

Joel B. Ard, WSBA # 40104

P.O. Box 11633

Bainbridge Island, WA 98110

(206) 701-9243

Joel@Ard.law

Attorneys for Plaintiffs

ALBRECHT LAW PLLC

By: 

David K. DeWolf, WSBA #10875

421 W. Riverside Ave., Ste. 614

Spokane, WA 99201

(509) 495-1246

Attorneys for Plaintiffs

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27

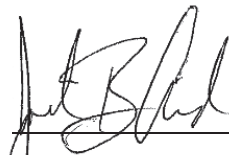
CERTIFICATE OF SERVICE

I certify under penalty of perjury under the laws of the United States of America that on June 1, 2020, I served the foregoing AMENDED COMPLAINT, together with a MOTION FOR CONTINUANCE, ARD DECLARATION, and PROPOSED ORDER; a MOTION TO SHORTEN TIME TO CONSIDER THE MOTION FOR CONTINUANCE and PROPOSED ORDER; all in *Cuevas v. Inslee*, via email per agreement between the parties, on the following:

comcec@atg.wa.gov
sgoolyef@atg.wa.gov
zach.jones@atg.wa.gov
brendan.selby@atg.wa.gov
jeffrey.grant@atg.wa.gov
jeffrey.even@atg.wa.gov
paul.weideman@atg.wa.gov
emma.grunberg@atg.wa.gov
rebecca.davilasimmons@atg.wa.gov
jennah.williams@atg.wa.gov
grace.summers@atg.wa.gov
mindy.nan@atg.wa.gov

ARD LAW GROUP PLLC

By



Joel B. Ard, WSBA # 40104
P.O. Box 11633
Bainbridge Island, WA 98110
(206) 701-9243
Joel@Ard.law
Attorneys for Plaintiffs

Exhibit C

☒ EXPEDITE☐ No hearing set☐ Hearing is set

Date: _____

Time: _____

Judge: _____

STATE OF WASHINGTON
DOUGLAS COUNTY SUPERIOR COURT

DAN SUTTON, MARK STRAUB, KYLE
STEINBERG, JIM WALKER,
CHRISTOPHER DAE QUINN, DENNIS
CARINO, DOUG BIANCHI, JESSE RAINS,
AND JOHN DIVIS,

Plaintiffs,

v.

JAY INSLEE, IN HIS OFFICIAL CAPACITY
AS GOVERNOR,

Defendant.

COMPLAINT FOR EMERGENCY
INJUNCTIVE RELIEF, DECLARATORY
RELIEF, AND TEMPORARY AND
PERMANENT RESTRAINING ORDER

Plaintiffs allege as follows:

I. PRELIMINARY STATEMENT

1. COVID-19 is a novel virus that can cause serious illness and can spread easily from person to person.

2. Chapter 72.06 RCW provides direction for how to prepare for and respond to a “novel virus” such as COVID-19. It places responsibility for doing so at the local level.

3. Now that it is clear that COVID-19 will not overwhelm hospital and other health care resources in Douglas County, there is no longer a “disaster” or any other emergency justifying the issuance of orders pursuant to RCW 43.06.220.

II. JURISDICTION AND VENUE

4. This Court has jurisdiction over the subject matter of this lawsuit.

5. Jose Luis Cuevas is a resident of Douglas County. Therefore, venue is proper with respect to the defendant pursuant to RCWA 4.92.010(1).

III. PARTIES

A. Dan Sutton

6. Mr. Sutton is a resident of Douglas County, Washington.

7. Mr. Sutton is a Douglas County Commissioner.

8. Mr. Sutton was the proprietor of the Cottage Inn restaurant in Wenatchee.

9. He celebrated the restaurant's 80th year of business this year, an institution in Wenatchee.

10. On March 16th he was forced to furlough 15 employees, 3 of whom were over 60 years of age, one with behavioral health disabilities.

11. Mr. Sutton had always been very proud of the fact that he was able to provide employment to protected class workers, human beings who at the best of times find it difficult to find gainful employment.

12. When the stay at home order was extended to the exclusion of the busy Memorial day Weekend it was the final blow to the business.

13. The death of an 80 year institution was one of the saddest days of Mr. Sutton's life.

14. The financial impact has been devastating, and the continued order as it stands and left unmodified has and will continue to destroy businesses and lives.

15. Mr. Sutton is certain that closure during the Memorial Day weekend will be the final death blow to many service and hospitality related businesses.

16. Mr. Sutton thereby has been harmed and is still being harmed by the Proclamation.

B. Mark Straub

17. Mr. Straub is a resident of Douglas County, Washington.

18. Mr. Straub is a Douglas County Commissioner.

1 19. Mr. Straub's household income has been significantly reduced as his wife is a sales
2 professional with a client base comprised almost solely of small businesses. She is compensated on
3 a commission basis.

4 20. As an elected official, Mr. Straub's ability to fulfill the responsibilities in serving
5 constituents has been deeply impacted.

6 21. The ongoing restrictions continue to prevent Mr. Straub from effectively
7 addressing their concerns and needs in a myriad of ways.

8 22. Due to the economy, Mr. Straub's youngest son will be returning to live with him
9 on a temporary basis until such time that local businesses begin hiring again, and he is able to secure
10 a position.

11 23. Mr. Straub's wife takes part in a weekly scheduled Bible Study group and has been
12 unable to participate in these meetings as they have been cancelled through the duration of the
13 order.

14 24. Mr. Straub thereby has been harmed and is still being harmed by the Proclamation.

15 **C. Kyle Steinberg**

16 25. Mr. Steinberg is a resident of Douglas County, Washington.

17 26. Mr. Steinberg is a Douglas County Commissioner.

18 27. As Commissioner, Mr. Steinberg has been unable to meet with constituents and
19 attend to issues that they have raised while restrictions on nonessential travel is in place.

20 28. Mr. Steinberg owns Wenatchee Body and Fender, LLC, an auto-body repair shop
21 in Wenatchee, WA.

22 29. Since Governor Inslee first announced the Stay Home, Stay Healthy Order, there
23 are less opportunities for his business to repair vehicles.

24 30. Mr. Steinberg took out a PPP loan from the SBA and has thus far been able to retain
25 all his employees.

31. However, Mr. Steinberg is over-staffed based on the volume of work, and will have to let employees go at the conclusion of the PPP loan-forgiveness period unless there is a significant increase in traffic and corresponding rebound in work opportunities.

32. An additional cause for the reduction in his business income includes, of the people who have encountered a need for repair services in the last two months, Mr. Steinberg has observed an extraordinarily high number of customers who are not able to afford the deductible because they recently became unemployed or have experienced a serious loss in income due to the effects of the Stay Home, Stay Healthy Order.

33. The Stay Home, Stay Health Order has limited Mr. Steinberg's childcare options while his children are unable to attend school, which has further reduced opportunities to work when work is available.

34. Mr. Steinberg's household income has been adversely impacted by The Stay Home, Stay Healthy Order.

35. Mr. Steinberg's spouse works in health care, and has been forced to work less because of the shutdown of elective surgeries.

36. Mr. Steinberg thereby has been harmed and is still being harmed by the Proclamation.

D. Jim Walker

37. Mr. Walker is a resident of Douglas County, Washington.

38. Mr. Walker lives, works, and employees people in Douglas County.

39. Mr. Walker is the owner of Lone Pine Fruit & Espresso, established in 2000 and Lone Pine Orchard, established in 1998.

40. Due to the Stay at Home order and the nature of the business, he has been unable to conduct business at its fullest.

41. This restriction is causing devastating financial hardship on not only to Mr. Walker, but also to his 13 employees and their families.

42. Mr. Walker and his employees depend on the influx of travelers on Highway 97 to support the business and their jobs. If he is unable to catch the Memorial Day Weekend business, his busiest weekend of the year, the outcome will be catastrophic to the financial stability of the business.

43. If more week, or even days, pass under these reduced conditions, Mr. Walker's business of twenty years will not survive.

44. Mr. Walker thereby has been harmed and is still being harmed by the Proclamation.

E. Dennis Carino

45. Mr. Carino is a resident of Douglas County, Washington.

46. Mr. Carino is a small business owner. Due to the "Stay at Home" order and the nature of his restaurant business, he have been unable to conduct profitable business resulting in devastating financial harm.

47. If Mr. Carino is unable to open for in-dining and catch the Memorial Day weekend, which is one of the busiest weekends of the year for his restaurant, the financial harm will be catastrophic and will likely cause the failure of his business.

48. Mr. Carino thereby has been harmed and is still being harmed by the Proclamation.

F. Jesse Rains

49. Mr. Rains is a resident of Douglas County, Washington.

50. Mr. Rains owns a local small business, Joe's East Sports Bar & Grill.

51. Due to the "Stay at Home" order and the nature of the business, Mr. Rains has been unable to continue to conduct business.

52. The financial harm has been devastating as Mr. Rains has already missed St. Patrick's Day, which is the busiest day for his business, as well as the local Apple Blossom Festival.

53. If Mr. Rains is unable to open and catch the Memorial Day weekend business, which is one of the busiest weekends of the year for the hospitality industry, the financial harm will be catastrophic and likely to cause the failure of his business..

54. Mr. Rains thereby has been harmed and is still being harmed by the Proclamation.

G. Christopher Dae Quinn

55. Mr. Quinn is a resident of Douglas County, Washington.

56. Mr. Quinn owns property in Douglas County, the city of East Wenatchee.

57. Mr. Quinn has commercial tenants unable to pay rent and portions of their expenses for extended periods of time as their businesses are required to be closed due to State orders.

58. This has caused these businesses to lay off or furlough hundreds of employees and has dropped his rental income to zero on these properties.

59. Mr. Quinn's real estate expenses meanwhile, such as taxes, maintenance, debt service, and insurance, continue to eat away at reserves.

60. Mr. Quinn's and his wife's salaries have been slashed by 40%. Being self-employed, they are not eligible for unemployment benefits, or Paycheck Protection Program funding of any sort.

61. Mr. Quinn is unable to attend weekly church services and worship with fellow believers. His spiritual life is actively being harmed, and in this difficult and emotional time he lacks the normal support he would receive from fellow church members.

62. Mr. Quinn thereby has been harmed and is still being harmed by the Proclamation.

H. Doug Bianchi

63. Mr. Bianchi is a resident of Douglas County, Washington.

64. Mr. Bianchi's business revenues are down at least 50% resulting in severe loss of personal income, inability to pay the mortgage on his family farm, and inability to properly maintain his agricultural crop.

65. Mr. Bianchi was forced to lay-off two employees.

66. Mr. Bianchi thereby has been harmed and is still being harmed by the Proclamation.

I. John Divis

67. Dr. Divis is a resident of Douglas County, Washington.

68. Dr. Divis has a Doctorate of Dental Surgery.

69. Dr. Divis owns a private dentistry practice.

70. Despite financial relief efforts by government officials, Dr. Divis' practice has experienced a significant loss of income, which has produced significant financial strain.

71. Dr. Divis expect a second wave of economic effects on the practice as people who have lost their businesses discontinue their regular dental care, negatively impacting their dental health as well.

72. Dr. Divis thereby has been harmed and is still being harmed by the Proclamation.

J. Jay Inslee

73. Jay Inslee is the Governor of the State of Washington.

IV. FACTUAL ALLEGATIONS

A. Conditions in Douglas County

74. As of May 22, 2020, there have been 137 confirmed cases of COVID-19 in Douglas County.¹

75. As of May 22, 2020, there have been 3 deaths due to COVID-19 in Douglas County.²

76. The cases have been easily handled by the existing health system infrastructure, which is now operating at below capacity.

77. Few if any healthcare workers have become infected, and the dreaded scenario in which the healthcare system was itself crippled by a workforce that had become carriers of COVID-19 never materialized.

78. There is no public disorder, energy emergency or riot in Douglas County.

79. The chief official of the Chelan-Douglas Health District, Dr. Malcolm Butler, asserts the District "is prepared for and capable of dealing with the threat to public health currently posed by COVID-19, as well as the additional threat posed by a phased reopening of the economy."

¹ <https://www.doh.wa.gov/Emergencies/NovelCoronavirusOutbreak2020COVID19/DataDashboard>

² *Id.*

1 80. Dr. Butler also “do[es] not anticipate a shortage of hospital or other health care
2 resources to deal with the COVID-19 pandemic.”

3 81. The emergency response center established jointly by Chelan and Douglas
4 Counties to prevent the hospital system from being overrun in the event of a mass outbreak has
5 partially deactivated and transitioned into “Recovery Mode,” which is defined as a non emergency
6 situation.

7 82. Dr. Butler has joined other public officials in Douglas County in requesting the
8 Governor loosen the restrictions imposed by the Proclamations in Douglas County. The governor
9 rejected this request.

10 83. There is no shortage of available hospital facilities to deal with foreseeable cases of
11 COVID-19 in Douglas County.³

12 84. Such “public disaster” will not come into existence if Proclamation 20-25.3 is lifted
13 and the county’s 70.26 RCW pandemic preparedness plan is implemented under the direction of
14 the Chelan-Douglas Health District.

15 85. The enforcement of Proclamations 20-05, 20-25, 20-25.1 and 20-25.3 have resulted
16 in grave damage to the physical, emotional, educational, interpersonal, religious, and economic
17 well-being of citizens in Douglas County.

18 **B. Pandemic Flu Preparedness**

19 86. Chapter 70.26 RCW, “PANDEMIC INFLUENZA PREPAREDNESS,” addresses
20 the response of state and local government to the outbreak of a novel virus that causes acute
21 respiratory distress, spreads rapidly, and has the potential of killing as many as 5,000 people in
22 Washington.

23 87. COVID-19 a novel virus that causes acute respiratory distress, spreads rapidly, and
24 has been predicted to have the potential of killing as many as 3,239 people in Washington.⁴

25
26 ³ *Id.*; *supra* n. 60, 61.

27 ⁴ <https://ihmecovid19storage.blob.core.windows.net/archive/2020-03-30/ihme-covid19.zip>

1 88. COVID-19 has killed under 1,000 people in Washington (931 as of 8:40pm May 10,
2 2020).⁵

3 89. COVID-19 is now predicted to kill a total of 1,189 people in Washington, or 248
4 more people in the indeterminate future than it has now killed in Washington.⁶

5 90. The threat posed by COVID-19 is well within the parameters of the plans
6 established by the state and county health departments pursuant to Chapter 70.26 RCW.

7 **C. The Nature of COVID-19**

8 91. COVID-19 is caused by a virus.⁷

9 92. The COVID-19 virus first began to infect humans in 2019.⁸

10 93. The COVID-19 virus is a new virus within the meaning of RCW 70.26.010(1).

11 94. COVID-19 can cause serious illness.⁹

12 95. COVID-19 spreads easily from person to person.¹⁰

13 96. Merriam-Webster defines “flu” as “1: influenza” and “2: any of several virus
14 diseases marked especially by respiratory or intestinal symptoms.”¹¹

15 97. Merriam-Webster defines “influenza” as “1a : an acute, highly contagious,
16 respiratory disease caused by any of three orthomyxoviruses . . .” and “1b: any of various human
17 respiratory infections of undetermined cause — not used technically.”¹²

18
19
20
21 ⁵ <https://www.doh.wa.gov/Emergencies/NovelCoronavirusOutbreak2020COVID19/DataDashboard>
(last visited at 1:00 pm May 11, 2020).

22 ⁶ <https://ihmecovid19storage.blob.core.windows.net/latest/ihme-covid19.zip> (last visited at 8:40 pm
23 May 10, 2020).

24 ⁷ <https://www.cdc.gov/coronavirus/2019-ncov/faq.html#Coronavirus-Disease-2019-Basics>

25 ⁸ *Id.*

26 ⁹ *Id.*

27 ¹⁰ *Id.*

¹¹ <https://www.merriam-webster.com/dictionary/flu>

¹² <https://www.merriam-webster.com/dictionary/influenza>

1 98. Merriam-Webster adds “Note: All types of influenza are commonly called “the
2 flu.”¹³

3 99. COVID-19 is a viral disease.¹⁴

4 100. The COVID-19 virus is a coronavirus.¹⁵

5 101. COVID-19 is marked especially by respiratory symptoms.¹⁶

6 102. COVID-19 is an acute, highly contagious respiratory disease.¹⁷

7 103. COVID-19 satisfies the common English definition of “flu” and “influenza” as
8 those words are used in RCW 70.26.010, whether or not the virus falls within the same scientific
9 classification taxonomy of seasonal influenza, the Asian flu of 1957-58, the Hong Kong flu in 1968-
10 69, or the 2006 Avian or bird flu.

11 104. The first case of COVID-19 was confirmed in Snohomish County, Washington on
12 January 21, 2020.¹⁸

13 105. Prior to January 21, 2020 no case had been reported anywhere else in the United
14 States.

15 **D. The IHME COVID-19 Models**

16 106. The Institute for Health Metrics and Evaluation (IHME) is an independent global
17 health research center at the University of Washington.¹⁹

18 107. IHME has modeled the likely course of COVID-19 in Washington state, including
19 predictions of cases, deaths, and use of health care resources, importantly including hospital beds,
20 intensive care unit beds, and invasive ventilators.²⁰

21 ¹³ *Id.*

22 ¹⁴ *Id.*

23 ¹⁵ *See supra* note 1.

24 ¹⁶ <https://www.cdc.gov/coronavirus/2019-ncov/faq.html#Symptoms-&-Testing>

25 ¹⁷ https://wwwnc.cdc.gov/eid/article/26/7/20-0282_article

26 ¹⁸ <https://www.snohd.org/495/COVID-19-General-Information>

27 ¹⁹ <http://www.healthdata.org/about>

²⁰ <http://www.healthdata.org/covid>

108. IHME's first predictive model was issued on March 25, 2019.²¹

109. IHME subsequently issued updated models on March 26, 2020; March 27, 2020; March 29, 2020; March 30, 2020; March 31, 2020; April 1, 2020; April 5, 2020; April 7, 2020; April 8, 2020; April 10, 2020; April 13, 2020; April 17, 2020; April 21, 2020; April 22, 2020; April 27, 2020; April 28, 2020; April 29, 2020; May 4, 2020; and May 8, 2020.²²

110. The March 25 IHME model and all subsequent IHME models are predicated on various assumptions, including that Washington practiced "social distancing," shorthand for the various mandates of the Proclamations.²³

111. The March 25 IHME model predicted between 312 and 2710 Washington State deaths due to COVID-19, with a mean estimate of 1429 deaths.²⁴

112. The March 25 IHME model also predicted that by April 14, 2020, at worst Washington state could have a shortage of available hospital beds of as many as 97 beds that day, increasing to an unmeetable need of over 635 beds by April 23, and declining thereafter until there was no predicted shortage by May 3.²⁵

113. The March 30 IHME model predicted between 462 and 3,239 Washington state deaths due to COVID-19, with a mean estimate of 1621 deaths.²⁶

114. The March 30 IHME model also predicted that by April 13, 2020, at worst Washington state could have a shortage of available hospital beds of as many as 37 beds that day, increasing to an unmeetable need of over 1270 beds by April 29, and declining thereafter until there was no predicted shortage by May 16.²⁷

²¹ <http://www.healthdata.org/covid/data-downloads>

²² *Id.*

²³ *Id.*

²⁴ <https://ihmecovid19storage.blob.core.windows.net/archive/2020-03-25/ihme-covid19.zip>

²⁵ *Id.*

²⁶ <https://ihmecovid19storage.blob.core.windows.net/archive/2020-03-30/ihme-covid19.zip>

²⁷ *Id.*

115. The April 1 IHME model predicted between 468 and 1636 Washington state deaths due to COVID-19, with a mean estimate of 978 deaths.²⁸

116. The April 1 IHME model no longer predicted that Washington would face any shortage of total hospital beds.²⁹

117. The April 1 IHME model did predict that, in a worst case scenario, Washington would face a shortage of available ICE beds beginning March 30, 2020 of 23 beds, peaking with a shortage on April 14 of 275 beds, and continuing through May 4, 2020.³⁰

118. The April 5 IHME model predicted between 557 and 741 Washington state deaths due to COVID-19, with a mean estimate of 632 deaths.³¹

119. The April 5 IHME model no longer predicated a potential shortage of either hospital beds or ICU beds.³²

120. No subsequent IHME model has predicted a potential shortage of any needed hospital resource.³³

121. The May 4 IHME model predicted between 1068 and 1304 Washington state deaths due to COVID-19, with a mean estimate of 1160 deaths.³⁴

122. The May 8 IHME model predicted between 1070 and 1189 Washington state deaths due to COVID-19, with a mean estimate of 1120 deaths.³⁵

123. The May 8 IHME model predicted no shortage of hospital beds or ICE beds.³⁶

²⁸ <https://ihmecovid19storage.blob.core.windows.net/archive/2020-04-01/ihme-covid19.zip>

²⁹ *Id.*

³⁰ *Id.*

³¹ <https://ihmecovid19storage.blob.core.windows.net/archive/2020-04-05/ihme-covid19.zip>

³² *Id.*

³³ <http://www.healthdata.org/covid/data-downloads>

³⁴ <https://ihmecovid19storage.blob.core.windows.net/archive/2020-05-04/ihme-covid19.zip>

³⁵ <https://ihmecovid19storage.blob.core.windows.net/latest/ihme-covid19.zip> (visited May 10, 2020)

³⁶ *Id.*

E. Other Relevant Hospital Resources

124. On March 30, 2020, the United States Army began assembling a 250-bed field hospital at CenturyLink Field in Seattle, to make additional hospital capacity available for the expected surge in required hospital beds.³⁷

125. That facility became ready to receive patients on or about April 5, 2020.³⁸

126. On April 8, 2020, without having received a single patient, the facility was disassembled and returned to the Army.³⁹

127. In late March or early April, the state procured 1,000 hospital beds and over 900 ventilators to assist hospitals responding to the COVID-19 emergency.⁴⁰

128. In late March or early April, the state leased the former Astria Regional Medical Center in Yakima to serve as a 250-bed field hospital if a need arose in Central Washington.⁴¹

F. Governor Inslee's Proclamations

129. On February 29, 2020, Governor Jay Inslee issued Proclamation 20-05.⁴²

130. Proclamation 20-05 stated that the worldwide outbreak of COVID-19 was a “public disaster that affects life, health, property or the public peace.”⁴³

131. Proclamation 20-05 a State of Emergency existed in all counties in the state of Washington and directed the implementation of the plans and procedures contained in the Washington State Comprehensive Emergency Management Plan.⁴⁴

³⁷ <https://www.kuow.org/stories/washington-state-to-return-centurylink-field-hospital-to-feds>

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² <https://www.governor.wa.gov/sites/default/files/proclamations/20-05%20Coronavirus%20%28final%29.pdf>

⁴³ *Id.*

⁴⁴ *Id.*

132. Governor Inslee based his declaration on Chapters 38.08, 38.52, and 43.06 RCW.⁴⁵

133. Proclamation 20-05 activated the organized militia of Washington State.⁴⁶

134. On March 23, 2020, Governor Inslee issued Proclamation 20-25, amending Proclamation 20-25 and entitled “Stay Home – Stay Healthy.” A copy may be found at <https://www.governor.wa.gov/sites/default/files/proclamations/20-25%20Coronavirus%20Stay%20Safe-Stay%20Healthy%20%28tmp%29%20%28002%29.pdf>

135. Proclamation 20-25 stated that “models predict that many hospitals in Washington State will reach capacity or become overwhelmed with COVID-19 patients within the next several weeks unless we substantially slow down the spread of COVID-19 throughout the state.”

136. No existing statute exists to address the potential problem of hospitals in Washington State reaching capacity or becoming overwhelmed with patients due to the rapid spread of a disease.

137. Proclamation 20-25 declared that “a State of Emergency continues to exist in all counties of Washington State.” Proclamation 20-25 imposed a “Stay Home – Stay Healthy Order throughout Washington State by prohibiting all people in Washington State from leaving their homes or participating in social, spiritual and recreational gatherings of any kind regardless of the number of participants, and all non-essential businesses in Washington State from conducting business, within the limitations provided herein.”⁴⁷

138. Proclamation 20-25 prohibited a list of activities “under the provisions of RCW 43.06.220(1)(h),” and provided that “Violators of this of this order [sic] may be subject to criminal penalties pursuant to RCW 43.06.220(5).”⁴⁸

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.*

139. On April 2, 2020, Governor Inslee issued Proclamation 20-25.1, “Extending Stay Home—Stay Healthy to May 4, 2020.”⁴⁹

140. Proclamation 20-25.1 stated that COVID-19 “has broadly spread throughout Washington State and is a significant health risk to all of our people, especially members of our most vulnerable populations.”⁵⁰

141. Proclamation 20-25.1 stated that there were at least 5,984 cases of COVID-19 in Washington State with 247 associated deaths, and “models predict that many hospitals in Washington State will reach capacity or become overwhelmed within the next few weeks unless we significantly slow its spread throughout the state.”⁵¹

142. Proclamation 20-25.1 also stated that “a large surge in the number of serious COVID-19 infections will compromise the ability of our health care system to deliver necessary health care services.”⁵²

143. Proclamation 20-25.1 stated that “a State of Emergency continues to exist in all counties of Washington State,” under the authority of Chapters 38.08, 38.52 and 43.06 RCW.⁵³

144. Proclamation 20-25.1 extended the provisions of Proclamation 20-25 “in full force and effect,” until 11:59 pm on May 4, 2020.⁵⁴

145. When Proclamation 20-25.1 was issued, the most recent IHME models predicted that hospitalizations would exceed available capacity in the state.⁵⁵

⁴⁹ [https://www.governor.wa.gov/sites/default/files/20-25.1%20-%20COVID-19%20-%20Stay%20Home%2C%20Stay%20Healthy%20Extension%20\(tmp\).pdf](https://www.governor.wa.gov/sites/default/files/20-25.1%20-%20COVID-19%20-%20Stay%20Home%2C%20Stay%20Healthy%20Extension%20(tmp).pdf)

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ <https://ihmecovid19storage.blob.core.windows.net/archive/2020-04-01/ihme-covid19.zip>

1 146. On May 4, 2020 Governor Inslee issued Proclamation 20-25.3, entitled “Adjusting
2 and Extending Stay Home—Stay Healthy to May 31, 2020.”⁵⁶

3 147. Proclamation 20-25.3 states that “health professionals and epidemiological
4 modeling experts predict that we have passed the peak of the progression [of the spread of the
5 virus] in the state,” but that “modelers agree that fully relaxing social distancing measures will
6 result in a sharp increase in the number of cases.”⁵⁷

7 148. Proclamation 20-25.3 relaxes some of the restrictions imposed by previous
8 Proclamations.⁵⁸

9 149. Proclamation 20-25.3 states that “the worldwide COVID-19 pandemic and its
10 progression in Washington State continue to threaten the life and health of our people as well as
11 the economy of Washington State, and remain a public disaster affecting life, health, property or
12 the public peace . . .”⁵⁹

13 150. Proclamation 20-25.3 states that under Chapters 38.08, 38.52 and 43.06 RCW “a
14 State of Emergency continues to exist in all counties of Washington State, that Proclamation 20-
15 05 and all amendments thereto remain in effect as otherwise amended . . .”⁶⁰

16 151. Proclamation 20-25.3 states that “Violators of this order may be subject to criminal
17 penalties pursuant to RCW 43.06.220(5). Further, if people fail to comply with the required social
18 distancing while engaging in the phased modifications of the mandatory social distancing
19 requirements, I may be forced to reinstate the prohibitions established in earlier proclamations.”⁶¹

20
21
22
23 ⁵⁶ <https://www.governor.wa.gov/sites/default/files/20-25.3%20-%20COVID-19%20Stay%20Home%20Stay%20Healthy%20-%20Reopening%20%28tmp%29.pdf>

24 ⁵⁷ *Id.*

25 ⁵⁸ *Id.*

26 ⁵⁹ *Id.*

27 ⁶⁰ *Id.*

⁶¹ *Id.*

152. Proclamation 20-25.3 does not assert that any model predicts that any hospital in Washington state is in any danger of reaching capacity or becoming overwhelmed.⁶²

153. Proclamation 20-25.3 does not assert that any model predicts that the hospital system in Washington state is in any danger of reaching capacity or becoming overwhelmed.⁶³

154. No model predicts that any individual hospital, nor the statewide hospital system in Washington state is at danger of reaching capacity or being overwhelmed.

155. No model predicts that, if and when the Chelan-Douglas Health District implements its pandemic flu preparedness and response plan in lieu of the Orders contained in Proclamation 20-25.3, the hospital system of Douglas County or the state of Washington will be in any danger of reaching capacity or becoming overwhelmed.

V. CAUSES OF ACTION

A. First Cause of Action: Declaratory Judgment

156. The allegations of the previous paragraphs are incorporated as if fully set forth herein.

157. Chapter 70.26 RCW addresses the potential for a “pandemic influenza” that could result in as many as five thousand deaths in Washington.

158. COVID-19 is within the definition of a “pandemic influenza,” which is “a new virus [that] appears in the human population, causes serious illness, and then spreads easily from person to person.” RCW 70.26.010.

159. None of the current projections for the ultimate number of deaths expected to result from COVID-19 predict more than a quarter of the number of deaths anticipated by RCW 70.26.010(3).

160. No prior projection for the ultimate number of deaths expected to result from COVID-19 predicted more than 5,000 deaths, below that anticipated by RCW 70.26.010(3).

⁶² *Id.*

⁶³ *Id.*

161. RCW 43.06.010(12) authorizes the Governor, “after finding that a public disorder, disaster, energy emergency, or riot exists within this state or any part thereof which affects life, health, property, or the public peace, proclaim a state of emergency in the area affected, and the powers granted the governor during a state of emergency shall be effective only within the area described in the proclamation.”

162. The only justification for declaring a state of emergency based on COVID-19 was when it appeared that the sudden spread of COVID-19 could overwhelm the hospital and other health care resources available to provide medical care to COVID-19 victims.

163. Because Chapter 70.26 RCW anticipates the potential for an influenza pandemic and prescribes the means to respond to such a pandemic, the appearance of a novel virus such as COVID-19 does not by itself constitute a “disaster” justifying the Proclamation of a state of emergency.

164. No current model projecting the spread of COVID-19 anticipates that hospital and other health care resources available to treat COVID-19 patients will be overwhelmed.

165. RCW 43.06.210 states that the Governor “must terminate said state of emergency proclamation when order has been restored to the area affected.”

166. There is no threat to public order in Douglas County.

167. The health care resources available in Douglas County have been reduced because of the prohibition on providing non-emergency health care.

168. Employees of health care facilities and providers serving Douglas County have been told that their wages will be reduced and their employment may end as a result of the inability of health care providers to earn income.⁶⁴

169. The state of emergency declared by Governor Inslee because of COVID-19 is no longer justified in Douglas County.

⁶⁴ https://www.wenatcheeworld.com/news/coronavirus/update-confluence-health-implements-salary-reductions-for-some-staff/article_ba3e7a36-7f68-11ea-94d5-bb7730a66883.html

170. The plaintiff is entitled to a declaratory judgment that the restrictions imposed by Governor Inslee's Proclamations are no longer enforceable.

B. Second Cause of Action: Injunctive Relief

171. The allegations of the previous paragraphs are incorporated as if fully set forth herein.

172. Governor Inslee's proclamation declaring a state of emergency throughout all counties in Washington was based on the potential for hospital and other health care resources to be overwhelmed by a "surge" of COVID-19 cases that would exceed the capacity of existing resources to handle.

173. Now that there is no model from any recognized public health authority projecting the potential for hospital and other health care resources to be overwhelmed, RCW 43.06.210 requires Governor Inslee to terminate the state of emergency proclamation "when order has been restored in the area affected."

174. Plaintiff has no adequate remedy at law for a continuation of the COVID-19 Proclamations beyond the time when they are justified.

175. Plaintiff is entitled to an injunction ordering Governor Inslee to terminate the COVID-19 Proclamations declaring a state of emergency in Douglas County.

176. Plaintiff is entitled to an injunction requiring Governing Inslee not to enforce the COVID-19 Proclamations in Douglas County.

C. Third Cause of Action: Declaratory Relief

177. The allegations of the previous paragraphs are incorporated as if fully set forth herein.

178. To whatever extent Chapter 43.06 RCW is not subject to judicial review as to the facts constituting an emergency, it is unconstitutional under at least Wash. Const. Art. II Sec. 1.

D. Fourth Cause of Action: Declaratory Relief

179. The allegations of the previous paragraphs are incorporated as if fully set forth herein.

180. To whatever extent Chapter 43.06 RCW allows the governor to proclaim an emergency to alter, override, or supersede existing statutes that govern the fact situation identified as an emergency, it is unconstitutional under at least Wash. Const. Art. II Sec. 1.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for the following relief:

1. For a declaratory judgment that Proclamation 20-08, Proclamation 20-09, and Proclamation 20-09.1 do not apply to Douglas County.
2. For injunctive relief requiring Governor Inslee to terminate any current order declaring a state of emergency in Douglas County.
3. For a Declaration that Chapter 43.06 RCW is unconstitutional.
4. For an award of Plaintiffs' costs of this suit, including attorney's fees.
5. For such other and further relief as this Court deems just and proper.

May 22, 2020.

ARD LAW GROUP PLLC

By: 

Joel B. Ard, WSBA # 40104

P.O. Box 11633

Bainbridge Island, WA 98110

(206) 701-9243

Joel@Ard.law

Attorneys for Plaintiffs

ALBRECHT LAW PLLC

By: 

David K. DeWolf, WSBA #10875

421 W. Riverside Ave., Ste. 614

Spokane, WA 99201

(509) 495-1246

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE


I certify under penalty of perjury under the laws of the United States of America that on May 22, 2020, I served the foregoing COMPLAINT in *Sutton v. Inslee*, together with a MOTION FOR TEMPORARY RESTRAINING ORDER, DECLARATION OF ARD IN SUPPORT OF THE MOTION, DECLARATIONS OF EACH PLAINTIFF, and PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW, all via email per agreement between the parties, on the following:

Kathryn Leathers, Kathryn.leathers@gov.wa.gov

Jeffrey Even, Jeffrey.even@atg.wa.gov

ARD LAW GROUP PLLC

By



Joel B. Ard, WSBA # 40104
P.O. Box 11633
Bainbridge Island, WA 98110
(206) 701-9243
Joel@Ard.law
Attorneys for Plaintiffs

Exhibit D

20-2-00369-21
CMP
Complaint
8187946



FILED
LEWIS COUNTY

2020 MAY -5 PM 3: 09

SUPERIOR COURT
CLERK'S OFFICE

☐ EXPEDITE
☐ No hearing set
☐ Hearing is set

Date: _____

Time: _____

Judge: Hon. _____

State Of Washington
Lewis County Superior Court

Katie Simper, on her own behalf and on behalf
of Austin Nelson, her child in Washington's
public schools; Kirsten Robbins, on her own
behalf and on behalf of Donald Argeris, her
child in Washington's public schools, and
Jennifer Anderson, on her own behalf and on
behalf of Eric Anderson, her child in
Washington's public schools

Plaintiffs,

v.

State of Washington, and Jay Inslee, Its
Governor,

Defendants.

No. **20 2 0036921**

Complaint for Declaratory
and Injunctive Relief

Plaintiffs allege as follows:

I. Preliminary Statement

1. In late 2019 or early 2020, a novel viral infection began circulating in Washington. The first hint of problems came in March 2020, when dozens of residents of two nursing homes in King County fell sick and many died; they were confirmed to have been infected with COVID-19, then running rampant in Hubei province, China.

Complaint for Declaratory and Injunctive Relief - 1

Ard Law Group PLLC

P.O. Box 13633
Burien, WA 98148
Phone: (206) 701-9243

- 1 2. Available evidence and modeling suggested a potential disaster: the virus spread rapidly by
2 aerosol, and resulted in so many serious illnesses that the state’s hospital capacity would soon
3 be overwhelmed.
- 4 3. Models suggested that within weeks, even with social distancing, Washington state would run
5 out of hospital beds, ICU beds, and ventilators.
- 6 4. It was feared that people who contracted COVID—or had other pressing medical needs—
7 would die from lack of access to care, where they would have survived if only we could save
8 the hospital system.
- 9 5. Many measures were implemented to avert this budding crisis. The U.S. Army built a field
10 hospital at a sports stadium in downtown Seattle; health care workers mobilized; businesses
11 began mandating work-at-home for workers whenever possible. Downtown Seattle became a
12 ghost town.
- 13 6. Before long, in response to the predicted disaster, Governor Inslee began mandating ever
14 tighter controls on movement and gathering. Washington pulled together to “flatten the curve.”
- 15 7. The goal of these constraints—voluntary and mandated—was to spread the rate of infection,
16 illness, and death out over time. Experts in epidemiology cautioned that the virus’ spread was
17 not really controllable, and the most we could hope for was to slow the rate.
- 18 8. Slowing the rate was viewed as a critical goal, because even if the same number of people
19 would eventually get infected, get sick, or get very sick, fewer would die *from lack of access*
20 *to medical care*.
- 21 9. In other words, with a limited stock of hospital beds, ICU beds, and ventilators, and knowing
22 that more people would need them than was available, the only course of action was to take
23 drastic steps to ensure the need was spread over time, instead of everyone needing the same
24 beds at the same time.
- 25 10. Based on available estimates of viral spread rates, severity of illness, percentage of infected
26 who needed hospitalization, length of hospital stays, and need for ventilators, a looming threat
27 was identified.

- 1 11. The Governor’s “Stay Home, Stay Healthy” order was intended to eliminate that threat to
- 2 public order by slowing the spread of disease.
- 3 12. RCW 43.06.220(1) authorizes the Governor, in the event of an emergency, to suspend a
- 4 number of constitutional rights, including the rights of assembly and travel, to protect life,
- 5 health and property.
- 6 13. However, over the weeks since the state has imposed limits on its citizens’ Constitutional
- 7 rights, more and more data have emerged regarding COVID-19. It has been almost unabated
- 8 good news.
- 9 14. Far fewer infected people need major medical intervention than expected at the outset.
- 10 15. The rate of spread has slowed beyond even early predictions of transmission under “social
- 11 distancing.”
- 12 16. Ventilators, far from being in short supply in Washington, became a surplus. We were fortunate
- 13 to be able to send 500 to New York, where the disease spread far more rapidly in the cramped
- 14 city, with its extreme reliance on public transportation.
- 15 17. The Army field hospital was dismantled without ever being used.
- 16 18. More good news emerged. Testing and study around the world developed treatment protocols
- 17 for those severely affected.
- 18 19. Among other things, many physicians urged far less use of mechanical ventilators than initially
- 19 suggested.
- 20 20. This greatly reduces the potential threat to Washington’s health care system of a lack of
- 21 capacity of ventilators.
- 22 21. Yet more good news emerged. Testing has repeatedly revealed that far more people have been
- 23 infected—but were completely asymptomatic—than initially assumed possible.
- 24 22. While it remains possible that an asymptomatic infection does not result in immunity, this
- 25 nonetheless shows that the ratio of infections to cases, of infections to severe cases, of
- 26 infections to cases requiring hospitalization, is lower than initially feared.
- 27

23. The predictive models have adopted these new facts—and they reveal yet more good news. It appears that the feared threat to Washington’s hospital system, of being overwhelmed by people suffering from COVID-19, is gone.

24. More good news: there have been far fewer COVID-19 deaths in Washington than any early model predicted.

25. More good news: there have been ZERO deaths in Washington from COVID-19 of people under age 20.

26. In fact, about 50% of the approximately 800 deaths in Washington have been among people over age 80.

27. It appears that Washington is similar to almost every state except New York: COVID-19, feared as a threat to the life and health of anyone in the state, turns out to be a selective killer, targeting the very old and infirm, those with serious other illnesses, and particularly those in nursing homes and other long-term care facilities.

28. Unfortunately, the Washington Department of Health has, to date, refused to disclose to the public the most relevant data: what percentage of the state’s deaths are from the nursing home and long term care population? What percentage have serious co-morbidities? What is the detailed age breakdown?

29. What we have learned over the course of the last month and a half is this: COVID-19 presents a statistically insignificant threat to the health of children, young adults, and healthy adults of middle and even slightly advanced age.

30. It spreads with many, many asymptomatic cases.

31. In nursing homes, and among Washingtonians with pre-existing illnesses, it can be a devastating and lethal disease.

32. Unfortunately, the Department of Health has clouded the issue, while failing for weeks to protect the vulnerable populations in Washington.

33. Today, we know far more than we knew in early March about COVID-19. We know that the emergency has been averted. We know that the threat to vulnerable populations remains. We know that there is no longer an emergency in the State.

34. That should be viewed as great news: we can address the vulnerable population with targeted measures. We can declare victory.

35. Unfortunately, the Governor insists that he, and he alone, can determine whether an emergency exists. He claims that it's an emergency if he says it's an emergency, and that no one—not the legislature, and not the courts—can gainsay him. He claims that the emergency can continue as long as he thinks it continues, and no one but he can say otherwise.

36. The Governor has assumed the sole power to determine whether a person in Washington can worship, can peaceably assemble, can work, can build needed housing, can offer living space for rent, can engage in any activity.

37. But the facts, and the science, are clear: when the entirety of public knowledge is examined, there is no public disorder or threat to public order in the State of Washington. The governor's claim to the contrary is demonstrably false.

38. The State was slow in its initial response to COVID-19 in nursing homes, but the hospitals turned their expertise over to helping staunch the infection in those vulnerable spaces. We have learned best practices for keeping those spaces as safe as possible in light of the serious health needs of the residents.

39. While our older and sicker relatives remain at greater risk, we now know that the emergency has been contained.

40. While the governor says otherwise, the facts are clear, and the Constitution does not authorize him to maintain infringements on Constitutionally guaranteed civil liberties on his mere say-so, with no avenue of review or redress.

41. Judicial review of the governor's claim of emergency must be available. Without review, a legitimate statute designed with flexibility to allow quick response to true emergent threats

becomes a tool for long-term imposition on Constitutionally guaranteed civil liberties from the mere whim of the state's executive.

42. In addition to the Constitutional guarantees that may only be overridden in the case of a genuine emergency, there is an additional reason the Governor's action is unconstitutional: it violates our state constitution's declaration of the "paramount duty" on the part of the state to make "ample provision for the education of all children residing within its borders" WASH. CONST. Art. IX, § 1.

43. As a result of Proclamations 20-08, issued on March 12, 2020, and supplemented by Proclamations 20-09 and 20-09.1, all public and private schools in the State of Washington have been closed through June 19, 2020.

44. Although the original and subsequent orders were based upon a belief that school closures were necessary because of the inability of our hospital system to handle the projected number of COVID-19 cases, current data indisputably establishes that hospitals now have sufficient capacity to deal with foreseeable cases of COVID-19.

45. At the time the Governor closed the public schools, he encouraged the substitution of "on-line" or "distance" learning for actual attendance in a school building. However, as the evidence in this case will clearly demonstrate, leaving children alone to engage in self-directed electronic learning is grossly inadequate to meet the educational needs of Washington children. And it clearly violates the State's constitutional duty to provide a basic education for all children residing in Washington.

II. Jurisdiction and Venue

46. This Court has jurisdiction over the subject matter of this lawsuit and over the parties to this lawsuit.

47. Katie Simper and is a resident of Lewis County. Therefore, venue is proper in this Court with respect to Defendant State of Washington pursuant to RCWA 4.92.010(1).

III. Parties

48. Katie Simper is a resident of Lewis County.

49. Katie Simper is the legal guardian of Austin Nelson, her grandson, who attends William F. West High School in the Chehalis School District.

50. Kirsten Robbins is a resident of Lewis County.

51. Kirsten Robbins' son Donald Argeris attends Orin C. Smith Elementary School in the Chehalis School District.

52. Jennifer Anderson is a resident of Lewis County. Her son Eric Anderson attends William F. West High School in the Chehalis School District.

53. The State of Washington is required by the state constitution to "make ample provision for the education of all children residing within its borders."

54. Jay Inslee is the Governor of the State of Washington, and heads the Executive Branch.

IV. Factual Allegations

The Governor's Orders

55. In determining whether there exists a state of emergency in Washington, and whether the infringement on civil liberties is addressed at steps that remedy that state of emergency, it is imperative to review the facts about relevant conditions in the state.

56. As of May 3, 2020, 841 people have died of COVID-19 in the State of Washington.¹

57. Of those, 52% are over age 80; 91% over age 60. Exactly zero are under age 20.

58. Whether or not this constitutes a state wide emergency justifying infringements on the civil liberties of all residents must be evaluated by, among other things, comparison to the similar status of normal public health issues in the state each year.

59. If the usage of health care resources in 2020 is roughly identical to past years, then any year is an emergency. If the death rate in 2020 is roughly identical to past years, then any year is an emergency. If the threat to public health posed by COVID-19 is not extremely dissimilar than

¹ Washington State Department of Health, COVID-19 in Washington State, Cumulative Confirmed Cases and Deaths, <https://www.doh.wa.gov/Emergencies/NovelCoronavirusOutbreak2020COVID19/DataDashboard>, (last visited May 5, 2020).

1 other threats to public health that regularly arise in the state, then “emergency” ceases to have
 2 meaning other than simply “Governor’s fiat.”

3 60. Thus, it is relevant to see, for example, that in 2018, 56,913, people died in the State of
 4 Washington, of which 988 died of Influenza and Pneumonia, the ninth leading cause of death
 5 in Washington.²

6 61. In 2017, 57,012 people died in the State of Washington, of which 1,037 died of Influenza and
 7 Pneumonia, the ninth leading cause of death in Washington.³

8 62. In 2016, 54,748 people died in the State of Washington, of which 809 died of Influenza and
 9 Pneumonia, the tenth leading cause of death in Washington.⁴

10 63. Whether or not a state of emergency exists across the entire state of Washington, among all
 11 residents and people, requiring impositions on the civil liberties of everyone in the state, must
 12 depend on the actual nature of the asserted emergency.

13 64. If any emergency is confined to certain small subsets of the population, the Governor’s
 14 statewide edict cannot be justified.

15 65. However, the Washington State Department of Health has thus far refused to release data on
 16 the number of COVID-19 deaths or cases among residents of nursing homes or long-term care
 17 facilities.

18 66. Looking at data from states which have been more transparent and open, it appears highly
 19 likely that the threat posed by COVID-19 in Washington is almost exclusively confined to long
 20 term care facilities and elderly, sick residents of the state.

21 67. By way of example, in the State of Illinois, there are 7,555 cases of COVID-19 at Long-Term
 22 care facilities among residents and staff, as of May 1, 2020. As of May 1, 2020, in the State of

24 ² Washington State Department of Health, Washington State Vital Statistics, DOH 422-099. (2018),
<https://www.doh.wa.gov/Portals/1/Documents/Pubs/422-099-2018-2010-VitalStatHighlights.pdf>

25 ³ Washington State Department of Health, Washington State Vital Statistics, DOH 422-099.
 26 (2017), <https://www.doh.wa.gov/Portals/1/Documents/Pubs/422-099-2018-2010-VitalStatHighlights.pdf>

27 ⁴ Washington State Department of Health, Washington State Vital Statistics, DOH 422-099.
 (2016), <https://www.doh.wa.gov/Portals/1/Documents/Pubs/422-099-2018-2010-VitalStatHighlights.pdf>.

Illinois there have been 1,082 COVID-19 deaths among residents and staff at Long-Term care facilities.⁵ As of May 3, 2020, there are a total of 61,499 cases of COVID-19 in the entire State of Illinois, and have been a total of 2,618 deaths.⁶

68. By way of example, in the State of Maryland, there are 3,218 confirmed cases of COVID-19 at nursing, assisted living, and group home facilities among residents (not including prisons or jails), and there have been 525 confirmed COVID-19 deaths among residents, as of April 29, 2020. As of April 29, 2020, there have been 1,489 confirmed cases of COVID-19 among staff at nursing, assisted living, and group home facilities, and 8 confirmed deaths of staff.⁷ As of May 3, 2020, in the State of Maryland, there have been a total of 26,408 confirmed cases of COVID-19, and 1,216 confirmed deaths. 2,144 COVID-19 cases and 519 COVID-19 confirmed deaths have been among those 80 years old or older; 5,993 COVID-19 cases, and 487 COVID-19 confirmed deaths have been among those who are between the ages of 60 and 79. There have been no confirmed deaths from COVID-19 for anyone under the age of 30, and no possible COVID-19 deaths for anyone under the age of 20.⁸

69. Emerging medical consensus tracks the lack of any COVID-19 deaths among children and youth in Washington.

70. Study after study has confirmed that there is practically no threat to youth and children from COVID, that they have extremely low risk of transmission to adults, and when symptomatic, have generally very mild symptoms.⁹

⁵ Illinois Department of Public Health, Long-Term Care Facility Outbreaks COVID-19, (2020), <http://www.dph.illinois.gov/covid19/long-term-care-facility-outbreaks-covid-19>.

⁶ Illinois Department of Public Health, Coronavirus Disease 2019, <http://www.dph.illinois.gov/covid19> (last visited May 4, 2020).

⁷ State of Maryland, Maryland COVID-19 in Congregate Facility Settings, <https://coronavirus.maryland.gov/pages/hcf-resources> (last visited May 4, 2020).

⁸ State of Maryland, COVID-19 statistics in Maryland, <https://coronavirus.maryland.gov/> (last visited May 4, 2020).

⁹ See, e.g., <https://www.medrxiv.org/content/10.1101/2020.03.26.20044826v1>; https://journals.lww.com/pidj/Fulltext/2020/05000/Coronavirus_Infections_in_Children_Including.1.aspx

71. As Dr. Anthony Fauci has said, describing the lack of any data to support excluding children from normal activities:

“One interesting feature of this novel coronavirus pandemic is that very few children have become sick with COVID-19 compared to adults,” said NIAID Director Anthony S. Fauci, M.D. “Is this because children are resistant to infection with SARS-CoV-2, or because they are infected but do not develop symptoms? The HEROS study will help us begin to answer these and other key questions.”¹⁰

72. If COVID-19, as a matter of fact, poses little to no threat to children and young adults, while those same people also pose little to no threat to themselves or others, there cannot be a state of emergency justifying impositions on their civil liberties.

73. If, in fact, COVID-19 illnesses and deaths are almost exclusively confined to those who are older or have serious existing illnesses, there cannot be a state of emergency justifying impositions on the civil liberties of every other resident of the state of Washington.

74. All evidence shows that the threat of COVID-19 is focused on long term care settings.

75. Yet the State’s response has not only been overbroad, by locking down healthy and unthreatened people, it has also been slow and inadequate in those areas of greatest threat.

76. For example, in Pierce County with just over 40 cumulative deaths and 1400 cases, a few congregate care settings made up the bulk of concentrations of the positive cases.

77. As hospitals and long-term care settings realized the problem, they shifted focus with hospitals attempting to help unprepared long-term care facilities. But personal protective equipment (“PPE”) and testing has not followed.

78. Even last week, nursing homes, rehab facilities and adult family homes were still struggling to obtain the proper PPE they need to care for their residents.

79. In some instances, the Department of Health has ordered a halt to testing of staff and residents at long-term care facilities for bureaucratic and paperwork related reasons, not in the interest of health of staff or residents.

¹⁰ <https://www.nih.gov/news-events/news-releases/study-determine-incidence-novel-coronavirus-infection-us-children-begins>

80. The DOH has found vendors to offer long-term care staff the needed training on dealing with COVID-19, but then decide to allow the vendor to charge the struggling facilities, instead of making the training available free as a matter of public health.

81. The DOH has fallen woefully short in guidance for staff treating person in those at-risk setting so that they can take the most appropriate and effective precautions to care for residents.

82. The state has also not disclosed which facilities have had outbreaks.

83. Nor has the state prioritized testing of workers in the long term care settings—in fact, it has blocked private testing in at least one instance!

84. Because workers in long-term care settings have the most direct contact with the highest-risk population in the state, testing them should be an imperative. Instead, the Governor has locked down the healthy population of the state while ignoring easy solutions that could address the actual health risks.

85. Long term care works plainly have the greatest potential to spread COVID-19 from client to client or from client to home.

86. Worse yet, the state has not disclosed the any information regarding the comorbidities of those who have dies with COVID-19.

87. Minnesota, by contrast, has made clear that over 99% of deaths in the state are among people with at least one serious co-morbidity.

88. In the face of a virus that poses an extreme risk to a narrow subset of the population, and one which is largely confined, immobile, and readily identifiable, there can not be, as a matter of fact, a state wide emergency.

89. The Governor has asserted otherwise.

A. Proclamations

1. Proclamation 20-25

90. Governor Inslee issued Proclamation 20-25 on March 23, 2020.

91. The Proclamation’s full title reads: “Proclamation By The Governor Amending Proclamation 20-05.”

92. The Proclamation's subtitle reads: "Stay Home—Stay Healthy."

93. The Proclamation identifies an earlier Proclamation issued by Governor Inslee, Proclamation 20-05, issued on February 29, 2020.

94. Proclamation 20-25 describes Proclamation 20-05 as "proclaiming a State of Emergency for all counties throughout the state of Washington."

95. Proclamation 20-25 describes Proclamation 20-05 as having proclaimed the State of Emergency "as a result of the coronavirus disease 2019 (COVID-19) outbreak in the United States and confirmed person-to-person spread of COVID-19 in Washington State."

96. Proclamation 20-25 identifies amendatory Proclamations 20-06, 20-07, 20-08, 20-09, 20-10, 20-11, 20-12, 20-13, 20-14, 20-15, 20-16, 20-17, 20-18, 20-19, 20-20, 20-21, 20-22, 20-23, and 20-24.

97. Proclamation 20-25 describes these amendatory Proclamations as "prohibiting certain activities and waiving and suspending specified laws and regulations."

98. Proclamation 20-25 describes these prohibitions, waivers and suspensions as an exercise of Governor Inslee's emergency powers.

99. Proclamation 20-25 cites RCW 43.06.220 as the law authorizing Governor Inslee to exercise his emergency powers in this manner.

100. Proclamation 20-25 gives "the continued worldwide spread of COVID-19, its significant progression in Washington State, and the high risk it poses to our most vulnerable populations" as the rationale for this alleged exercise of Governor Inslee's emergency powers.

101. Paragraph 5 of Proclamation 20-25 states:

WHEREAS, models predict that many hospitals in Washington State will reach capacity or become overwhelmed with COVID-19 patients within the next several weeks unless we substantially slow down the spread of COVID-19 throughout the state;

102. The Governor's reasoning for issuing Proclamation 20-25 was that hospitals in Washington state could have become overwhelmed with COVID-19 patients within several weeks, according to models as of March 23, 2020.

103. The potential overwhelming of hospital resources constituted the threat to public order that justified the exercise of the governor's emergency powers.

104. The family of viruses that includes COVID-19, although potentially deadly in elderly patients, particularly with comorbidities, is less dangerous to children. These viruses "seem to less commonly affect children and to cause fewer symptoms and less severe disease in this age group compared with adults, and are associated with much lower case-fatality rates."¹¹

105. School closures will not only deprive children of their constitutional right to an education, but may pose independent health risks. For example, "COVID-19, via these school closures, may exacerbate the epidemic of childhood obesity and increase disparities in obesity risk."¹²

The Harm to Plaintiffs

106. Austin Nelson attends William F. West High School in the Chehalis School District.

107. Prior to the closure of the school resulting from Governor Inslee's Proclamation(s), Austin had learning challenges that resulted in the preparation of an IEP (individualized education program).

108. The IEP was designed to insure that Austin could return to meeting grade-level expectations.

109. Katie Simper works all day as a health care worker and is unable to supervise Austin during what would be the school day.

110. Although the school has attempted to provide on-line and distance learning substitutes for attendance at school, they are inadequate to meet Austin's educational needs.

111. Austin needs the supervision and encouragement that results from attendance at an actual school where teachers are present to assist him.

¹¹ Petra Zimmerman and Nigel Curtis, *Coronavirus Infections in Children Including COVID-19: An Overview of the Epidemiology, Clinical Features, Diagnosis, Treatment and Prevention Options in Children*, THE PEDIATRIC INFECTIOUS DISEASE JOURNAL, Volume 39, Number 5 (May 2020), 355-367.

¹² Andrew Rundle, et al., *COVID-19-Related School Closings and Risk of Weight Gain Among Children*, OBESITY, published 30 March 2020, <https://onlinelibrary.wiley.com/doi/full/10.1002/oby.22813>

1 112. Austin is not receiving the basic education that is his right.

2 113. Donald Argeris, aged 9, is a student in the third grade at Orin C. Smith Elementary School
3 in the Chehalis School District.

4 114. Donald's mother, Kirsten Robbins, resides in a home with her extended family. There are
5 seven children living in the house.

6 115. Donald is the oldest.

7 116. Kirsten Robbins has neither the training nor the resources to provide home-schooling for
8 Donald.

9 117. Donald has been offered on-line and "distance learning" as a substitute for attendance at
10 the elementary school.

11 118. He is recommended to spend an at least an hour a day online, attempting to learn.

12 119. Donald requires the supervision of teachers and other educators who can ensure that he is
13 engaged in learning.

14 120. Donald does not succeed in a non-structured environment, surrounded by younger children,
15 and no other adult in the home (including his mother) is able to provide the structure that he
16 needs.

17 121. Donald is not receiving the basic education that is his right.

18 122. Eric Andersen is a freshman.

19 123. His parents are divorced, and he spends the weekdays with his father.

20 124. His father works in construction, and is not home during the day. Additionally, his home
21 does not have internet access.

22 125. Eric therefore must attempt to cram a week of school in over the weekends with his mother,
23 while he cannot have meaningful contact with his teachers, even virtually.

24 126. Eric is not receiving the basic education that is his right.

V. Causes of Action

First Cause of Action: Declaratory Judgment

127. Art. IX, § 1 of the Washington State Constitution imposes upon the State of Washington the “paramount duty to make ample provision for the education of all children residing within its borders”

128. As a result of Art. IX, § 1 of the state constitution, all children in the State of Washington have a positive right to receive a basic education.

129. Governor Jay Inslee is the head of the Executive Branch of the government of the State of Washington.

130. As Governor and head of the Executive Branch, Inslee is required to comply with Art. IX, § 1 of the state constitution.

131. The Governor’s Proclamations prevent the public schools from being able to provide the education that is promised by Art. IX, § 1 of the state constitution.

132. The Plaintiffs are entitled to a declaration from this Court that the Governor’s Proclamation(s) closing the public schools are in violation of the state constitution

Second Cause of Action: Injunctive Relief

133. Plaintiffs incorporate the foregoing Paragraphs as if fully restated herein.

134. Governor Inslee’s Proclamations ordering the closure of the public schools in Washington violate Art. IX, § 1 of the state constitution.

135. As a result of the closure of the public schools, the Plaintiffs have suffered and (unless enjoined by this Court) will continue to suffer irreparable harm to their right to an education.

136. Plaintiffs have no remedy at law adequate to redress the harm threatened by the continuation of the Governor’s orders.

137. Plaintiffs are therefore entitled to injunctive relief to prevent future harm to their right to an education.

VI. Prayer for Relief

WHEREFORE, Plaintiffs pray for the following relief:

1. For a declaratory judgment that Proclamation 20-08, Proclamation 20-09, and Proclamation 20-09.1 are unconstitutional for failure to comply with with Art. IX, § 1 of the Washington State Constitution.
2. For injunctive relief requiring Governor Inslee to terminate any current order requiring the closure of Washington schools.
3. For injunctive relief requiring that any future order closing the public schools be based on a documented risk of substantial physical harm to the students attending those schools.
4. For an award of Plaintiffs' costs of this suit, including attorney's fees.
5. For such other and further relief as this Court deems just and proper.

May 5, 2020.

Ard Law Group PLLC

By: 

Joel B. Ard, WSBA # 40104
P.O. Box 11633
Bainbridge Island, WA 98110
(206) 701-9243
Joel@Ard.law
Attorneys for Plaintiffs

Albrecht Law PLLC

By: 

David K. DeWolf, WSBA #10875
421 W. Riverside Ave., Ste. 614
Spokane, WA 99201
(509) 495-1246
david@albrechtlawfirm.com
Attorneys for Plaintiffs

Certificate Of Service

I certify under penalty of perjury under the laws of the United States of America that on
DATE, 2020, I served the foregoing DOCUMENT in Simper v. Inslee, CASE NO., via email per
agreement between the parties on the following:

--	--

Ard Law Group PLLC

By



Joel B. Ard, WSBA # 40104
P.O. Box 11633
Bainbridge Island, WA 98110
(206) 701-9243
Joel@Ard.law
Attorneys for Plaintiffs

Exhibit E

1 IN THE SUPERIOR COURT OF THE STATE OF WASHINGTON
2 FOR THE COUNTY OF CHELAN
3

4 JOSE LUIS CUEVAS, et al,)
5 Plaintiffs,)
6 vs.) No. 20-2-00352-04
7 JAY INSLEE, in his official)
8 capacity as Governor,)
9 Defendant.)
-----)

10
11
12 DEPOSITION OF MALCOM D. BUTLER, M.D.

13 Taken at the instance of the Defendant
14
15

16 June 8, 2020

17 10:00 a.m.

18 139 South Worthen

19 Wenatchee, Washington
20
21

22
23 BRIDGES REPORTING & LEGAL VIDEO
24 Certified Shorthand Reporters
25 1312 N. Monroe Street
Spokane, Washington 99201
(509) 456-0586 - (800) 358-2345

1 BE IT REMEMBERED that the deposition of MALCOM
2 D. BUTLER, M.D., was taken in behalf of the Defendant
3 pursuant to the Washington Rules of Civil Procedure
4 before William J. Bridges, Certified Shorthand Reporter
5 for Washington, Idaho and Oregon, on Monday, the 8th
6 day of June, 2020, at the Office of the Attorney
7 General, 139 South Worthen, Suite 100, Wenatchee,
8 Washington, commencing at the hour of 10:00 a.m.

9
10 *

*

*

11
12 APPEARANCES:

13
14
15 For the Plaintiffs: DAVID K. DeWOLF, ESQ.
16 (via Zoom) Albrecht Law PLLC
Attorneys at Law
421 West Riverside Avenue
Suite 614
Spokane, WA 99201
18 (509) 495-1246
david@albrechtlawfirm.com
19

20
21 For the Defendant: ZACHARY PEKELIS JONES, ESQ.
Assistant Attorney General
22 (via Zoom) 800 Fifth Avenue
Suite 2000
Seattle, WA 98104
23 (206) 332-7089
zach.jones@atg.wa.gov
24 (206) 332-7089
25

APPEARANCES (Cont'd).

For the Defendant: JEFFREY T. EVEN, ESQ.
Deputy Solicitor General
(via Zoom) 1125 Washington Street N.E.
Olympia, WA 98504
(360) 586-0728
jeffrey.even@atg.wa.gov

For the witness: CHARLES D. ZIMMERMAN, ESQ.
Ogden Murphy Wallace
Attorneys at Law
1 Fifth Street
Suite 200
Wenatchee, WA 98807
(509) 662-1954
czimmerman@omwlaw.com

Also present: JENNAH WILLIAMS (via Zoom)

*

*

*

I N D E X:

JOSE LUIS CUEVAS, et al vs. JAY INSLEE

No. 20-2-00352-04

June 8, 2020

T E S T I M O N Y

MALCOM D. BUTLER, M.D.

PAGE NO:

Examination by Mr. Jones

6 - 94

PRODUCTION REQUESTS:

(None)

E X H I B I T S:

No:	Identification:	Page:
1	Proclamation by the Governor Amending Proclamations 20-05, 20-25, 20-25.1, 20-25.2 and 20.25.3 and 20-25.4, Transition from "State Home - Stay Healthy" to "Safe Start - Stay Healthy" County-by-County phased reopening, Bates 000081 - 85	18
2	E-mail string, 5/14/20, 5/18/20, Lorena Orozco, Marc Straub, Board of Health, Francis Collins, Malcolm Butler, Tiana Rowland; Subject: BOH Packet for Monday, May 18, 2020, Bates 000201 - 202	40
3	Declaration of Marc Straub in Support for Motion for Temporary Restraining Order, 5/28/20, Bates 000059 - 66	46
4	E-mail string, 5/14/20, 5/18/20, 5/19/20, Malcolm Butler, Marc Straub, Lorena Orozco, Board of Health, Francis Collins, Tiana Rowland; Subject: BOH Packet for Monday, May 18, 2020, Bates 000204 - 207	70
5	E-mail string, 5/14/20, 5/18/20, 5/19/20, 5/20/20, Marc Straub, Malcolm Butler, Lorena Orozco, Board of Health, Francis Collins, Tiana Rowland; Subject: BOH Packet for Monday, May 18, 2020, Bates 00000196 - 199	76
6	E-mail, 5/28/20, Malcolm Butler to Marc Straub; Subject: Deceit	86

5

1 (MALCOM D. BUTLER, M.D., called as a witness
2 by the Defendant, being first duly sworn to tell the
3 truth, the whole truth and nothing but the truth, was
4 examined and testified as follows:)

5
6
7 EXAMINATION

8
9 BY MR. JONES:

10 Q. Good morning, Dr. Butler. I just introduced
11 myself earlier. My name is Zachary Pekelis Jones,
12 P-E-K-E-L-I-S, and I'm an attorney for Governor Inslee
13 in this matter.

14 Have you ever had your deposition taken
15 before in any court proceeding.

16 A. Yes.

17 Q. How many times?

18 A. Gosh, I don't remember. I think about four
19 in my career.

20 Q. And what were the nature of those
21 proceedings?

22 A. Yeah. They've been a long time ago. All of
23 them were medically-related.

24 One of them was in my role as staff, what's
25 called medical staff officer at Central Washington

6

1 So I used my asthma inhaler this morning.

2 Q. Any medications or other substances that
3 might impair or inhibit your ability to understand my
4 questions and answer them truthfully?

5 A. No.

6 Q. Okay. Any other reason why you would be
7 unable to understand my questions or answer them
8 truthfully?

9 A. Not on my part, no.

10 Q. Okay. And did you receive a subpoena and a
11 deposition notice for today's deposition?

12 A. Yes.

13 Q. Okay. I'd like to just begin talking about
14 your educational and professional background briefly.

15 What are your current professional
16 positions?

17 A. I'm currently the Chief Medical Officer at
18 Columbia Valley Community Health. I am a physician
19 with expertise in family medicine.

20 Q. And how long have you been in that position
21 at Columbia Valley Community Health?

22 A. 27 years.

23 Q. And are there any other positions that you
24 currently hold professionally?

25 A. I am currently the health officer for Chelan

10

1 and Douglas Counties, local health jurisdiction.

2 Q. And is that the Chelan-Douglas County Health
3 District?

4 A. Correct.

5 Q. So, we may refer to that entity repeatedly
6 today. Just for short, I'm going to refer to it as the
7 Health District.

8 Does that make sense to you?

9 A. Yes.

10 Q. Okay. And how long have you been in
11 that position as health officer with the Health
12 District?

13 A. Since April 20, 2020.

14 Q. April 20th, 2020?

15 A. Correct.

16 Q. Any other current professional positions
17 that you hold?

18 A. I sit on various committees, but none, I
19 wouldn't consider them as sort of professional titled
20 positions or anything like that.

21 I have a faculty appointment at the
22 University of Washington, that sort of thing.

23 Q. Understood. You mention that you have an
24 expertise in family medicine. Could you just describe
25 the educational credentials that you have received in

11

1 the course of that practice?

2 A. I have a B.A. in philosophy from Cornell
3 University.

4 Q. Uh-huh.

5 A. I have a Medical Doctorate from the
6 University of Washington.

7 I am board certified in family medicine,
8 having completed a three-year family medicine residency
9 at the University of California, Los Angeles.

10 Q. Any other education or training in the
11 course of your medical degree -- medical experience?

12 A. I have had continuous additional training
13 throughout my medical career.

14 Q. Do you have any training specifically in the
15 field of public health?

16 A. No.

17 Q. Okay. Other than your experience as the
18 Health Officer with the Chelan-Douglas County Health
19 District, do you have experience in the field of public
20 health?

21 A. In as much as public health relates to a
22 primary care practice in a rural community, yes.

23 Q. Have you had a specific position in public
24 health management or administration?

25 A. No.

12

1 Q. Turning to your experience with the Health
2 District, you began relatively recently.

3 Can you describe the circumstances under
4 which you came to occupy the position as Health Officer
5 with the Health District?

6 A. I was approached by Barry Kling who manages
7 the Health District. He asked if I would be willing to
8 step up during this pandemic to assist the Health
9 District.

10 The prior health officer is a retired oral
11 surgeon. And there were concerns about his capacity to
12 actively direct and manage this crisis for the Health
13 District.

14 Q. And why was that, if you know?

15 A. Because of his age and time out of practice.

16 Q. And what was the name of the prior Health
17 Officer?

18 A. Francis Collins.

19 Q. And is he still serving in an emeritus
20 capacity for the Health District?

21 A. Yes.

22 Q. Could you explain what the hierarchy of the
23 Health District leadership is? For example, to whom do
24 you report and who reports to you?

25 A. I report to the Board of Health. There is

13

1 Doug England are all County Commissioners. Two from
2 Douglas County, two from Chelan County.

3 Ruth Esparza is a local attorney, and I
4 believe on the Wenatchee City Council. And there's a
5 woman named Sharon who I know lives in Leavenworth.
6 I'm not sure what her role or other titles might
7 be.

8 Q. Is she an elected official, as well?

9 A. I do not know.

10 Q. And is there also a Mr. John Sterk who's on
11 the board?

12 A. I believe so, yes.

13 Q. Prior to becoming the Health Officer in
14 April of 2020, did you know any of the board members
15 personally?

16 A. No.

17 Q. Do you know if any of the board members is
18 an expert or professional in any medical field?

19 A. I'm not aware that any of them have any
20 medical expertise, no.

21 Q. So, I guess none is an expert in -- none of
22 them expert or professional in epidemiology?

23 A. I'm sorry. I don't know what background any
24 of them have in epidemiology.

25 Q. And do you know whether any of them have a

15

1 certain team members of the ACH. And we had regular
2 meetings. Various members of the Health District were
3 also participating in various roles. It was largely in
4 that way.

5 As a primary care provider I am mandated to
6 report infectious diseases and other things to the
7 Health District. I have worked with them regularly in
8 that capacity, and in working on contagion throughout
9 the years.

10 Q. Do you know what Mr. Kling's professional
11 training is in?

12 A. I do not know specifically. I know that he
13 previously had a role in the Midwest. I'm aware that
14 he has held similar positions in the past. I do not
15 know what his actual academic work has been.

16 Q. Based on your experience working with him at
17 the Health District and prior, would you describe Mr.
18 Kling as knowledgeable and experienced in the field of
19 public health?

20 A. Yes.

21 Q. So, I would like to turn to our first
22 exhibit today, which is tab H.

23 A. Okay. There are no tabs. How would I find
24 tab H?

25 MR. JONES: Right here (indicating).

17

1 Q. So, this second paragraph on page 81 refers
2 to Proclamations 20-25 and amendatory proclamations
3 that prohibit "all people in Washington State from
4 leaving their homes except to participate in essential
5 services or essential work and preventing all
6 non-essential businesses in Washington State from
7 conducting business, within the limitations therein."

8 Is that correct?

9 A. Yes.

10 Q. And so I'm going to refer to those
11 proclamations collectively as the Stay Home - Stay
12 Healthy proclamation, or Stay Home - Stay Healthy
13 order.

14 Does that make sense to you?

15 A. Yes.

16 Q. Now, based on your medical training and
17 expertise, did you agree with the Governor's decision
18 to issue the Stay Home - Stay Healthy order?

19 A. Yes.

20 Q. Why?

21 A. It was clear that social distancing was the
22 most effective tool we had to combat the transmission
23 of the virus and the COVID-19 pandemic. It was clear
24 that in order to avoid morbidity and mortality
25 throughout the state the economy had to be sufficiently

20

1 curtailed that there was little incentive for
2 individuals to leave their homes.

3 Q. If you turn your attention to the third
4 Whereas paragraph on page 81, read along silently while
5 I read aloud. "Whereas, the COVID-19 disease, caused
6 by a virus that spreads easily from person to person
7 which may result in serious illness or death and has
8 been classified by the World Health Organization as a
9 worldwide pandemic, has broadly spread throughout
10 Washington State and remains a significant health risk
11 to all of our people, especially members of our most
12 vulnerable populations."

13 Did I read that correctly?

14 A. Yes.

15 Q. Do you agree with this statement by the
16 Governor that COVID-19 remains a significant health
17 risk to all of our people, especially members of our
18 most vulnerable populations?

19 A. Zach, can I clarify your question?

20 Q. Sure.

21 A. You used the word "remains." Are you
22 referring to what is before me here in this document,
23 or are you referring to today as of January -- June
24 8?

25 Q. As of today, June 8, would you agree that

21

1 population from the spread, especially when there is
2 such a large asymptomatic proportion of infectious
3 people.

4 Q. Do you have an opinion on whether, based on
5 the scientific evidence you have seen, asymptomatic or
6 pre-symptomatic sufferers of COVID-19 can transmit the
7 virus to others?

8 A. Absolutely.

9 Q. What is your opinion?

10 A. What is my opinion on what, Zach?

11 Q. Sir, my question is whether you have an
12 opinion on --

13 A. Oh, sorry.

14 Q. -- that subject.

15 A. Yes. So, my opinion is that, yes,
16 absolutely the disease is transmitted by asymptomatic
17 individuals.

18 Q. And as well as pre-symptomatic individuals,
19 right?

20 A. Pre-symptomatic are also asymptomatic, yes.

21 Q. So, in light of that, and the risk that it
22 presents to more vulnerable populations, would you
23 agree, kind of slightly changing the wording of this
24 third Whereas paragraph, would you agree that COVID-19
25 today remains a significant public health risk in

23

1 Washington?

2 A. Yes.

3 Q. And does it remain a significant public
4 health risk in Chelan County?

5 A. Yes.

6 Q. If you will turn to page 82 to the top
7 Whereas paragraph there.

8 A. (Witness complied).

9 Q. And would you just read that paragraph at
10 the top to yourself silently, and then I will ask you a
11 question or two about it when you are done.

12 (Pause in the proceedings).

13 A. I'm done.

14 Q. Okay. Would you agree that modelers
15 continue to agree that fully relaxing social distancing
16 measures will result in a sharp increase in the number
17 of COVID-19 cases?

18 A. Yes.

19 Q. Okay. Turning to the next page, page 83.

20 A. (Witness complied).

21 Q. And this is the top full Whereas paragraph
22 on page 83. Just read along silently as I read
23 aloud.

24 "Whereas, the worldwide COVID-19 pandemic
25 and its progression in Washington State continue to

24

1 threaten the life and health of our people as well as
2 the economy of Washington State, and remain a public
3 disaster affecting life, health, property or the public
4 peace."

5 Do you see where I read that?

6 A. Yes.

7 Q. Do you agree that the worldwide COVID-19
8 pandemic and its progression in Washington State
9 continue to threaten the life and health of our people
10 as well as the economy of Washington State and remain a
11 public disaster affecting life, health, property or the
12 public peace?

13 A. Yes.

14 Q. Setting the document aside now, in your
15 opinion, Dr. Butler, would you say that the state's
16 response to the COVID-19 pandemic has been reasonable
17 in light of the available data and generally accepted
18 public health practices?

19 A. Can you please explain what you mean by
20 "reasonable"?

21 Q. Well, is it consistent with the available
22 data and generally accepted public health practices?

23 A. I believe that the proclamation is
24 consistent and reasonable, based on my knowledge of
25 COVID-19, yes.

25

1 working closely with. I have sought their guidance. I
2 have participated in communications.

3 Q. And with whom have you communicated with the
4 State Department of Health?

5 A. Kathy Lofy, Scott Lindquist, John Weisman,
6 Charisa, whose last name isn't coming to me right now,
7 Medical Director of -- Well, maybe it's -- Anyway,
8 Medical Director of Medicaid. And a couple of other
9 folks in various capacities that I don't recall.

10 Q. Has the Health District shared or received
11 data or information from the State Department of
12 Health?

13 A. I have personally reviewed the State
14 Department of Health web page and absorbed the
15 information that they present there and update daily.

16 I have received multiple communications
17 regarding guidance, both from the CDC and the State
18 DOH. Many of them communicated through the State
19 DOH.

20 I am aware that the state and the local --
21 our local health jurisdiction are participating in
22 gathering the data local to the state and uploading it
23 to the state database.

24 Q. And how would you say the resources that the
25 State Department of Health has at its disposal, how

28

1 does that compare to what the Health District has?

2 A. They appear to have three orders of
3 magnitude more resources than we have at our local
4 Health District.

5 Q. Has the Health District received any
6 resources from the State?

7 A. The Health District has taken advantage of
8 contact tracing which has been offered through the
9 state.

10 And then other than the data and the
11 guidance and essentially pushing out guidance, I'm not
12 aware of any other specifics. But again that really
13 has not been part of my role.

14 Q. Understood. What role did the Board of
15 Health play in the Health District response to the
16 COVID-19 pandemic?

17 A. Since my time in this position?

18 Q. Yes.

19 A. Since my time in this position I have
20 participated in two Board of Health meetings, and
21 probably four emergency meetings.

22 My impression at the initial April 20 Board
23 of Health meeting was that they were soliciting
24 information in reports, and that they were venting a
25 very strong desire to bring decision-making and control

29

1 I do recall it was pointed out to the board
2 members at that time that the statutes still empowered
3 the health officer to levy such fines. But the board
4 still took that action.

5 Outside of those two actions and their
6 directive to create the two variance proposals, I do
7 not recall other direct guidance as regards the
8 management of the pandemic.

9 Q. Would you describe any tension or conflict
10 or disagreement between the Board of Health and the
11 professional staff of the Health District regarding the
12 response to the COVID-19 pandemic?

13 A. Will you please repeat the first part of
14 that question?

15 Q. Sure. My question is whether you perceived
16 any tension or disagreement or conflict between the
17 Board of Health on the one hand and professional
18 staff in the Health District, such as yourself, on the
19 other hand, regarding the District's response to
20 COVID-19?

21 A. Yes.

22 Q. Please describe.

23 A. During my time in this position it has felt
24 that a great deal of energy has been exerted to address
25 the concerns of the members of the Board of Health,

32

1 that the Governor's proclamation was unnecessary and
2 destroying the local economy without appropriate
3 observable gains.

4 I think there was a tension between the
5 medically prepared and epidemiologically prepared
6 individuals who recognized the potential danger of the
7 pandemic, and I felt that we were continuously required
8 to exert our great concern and repeatedly point out the
9 biology and transmissibility of the virus and the
10 rationale for the Governor's proclamation.

11 Most specifically the elected officials
12 appeared to have an agenda that was very pro-opening of
13 the economy and an effort to minimize the current
14 and future impact of the pandemic within our
15 jurisdiction.

16 It has been quite frustrating, I believe,
17 certainly for myself and I'm aware for Mr. Kling to be
18 put in a position of trying to utilize an extremely
19 small resource in the local Health District to manage
20 an enormous geographic area with a very diverse
21 population in the midst of the most significant
22 worldwide pandemic in a hundred years, and also to
23 be exerting energies to help the Board of Health
24 members appreciate the gravity from a physiologic and
25 medical perspective, the potential gravity of the

1 pandemic.

2 Repeatedly it felt to me that since we had
3 not had multiple deaths, since our hospitals were not
4 overwhelmed, since the vast majority of the individuals
5 in our jurisdiction tolerate the infection without
6 significant morbidity, that therefore the Stay Home -
7 Stay Safe order could be rescinded.

8 Q. That was the view of the Board of Health
9 members you just described?

10 A. I felt a great deal of energy was extended
11 against that opinion, and that opinion, yes, was of the
12 Board of Health. Again, not all of them. Largely, the
13 elected members.

14 Q. You mention that some of the elected
15 officials had an agenda that was very in favor of
16 opening the economy.

17 Is that right?

18 A. Correct.

19 Q. Okay. At any point did you feel that
20 that agenda made it harder for you to do your job to
21 protect the public health in Chelan County and Douglas
22 County?

23 A. I felt that I was exerting a great deal of
24 energy to counter that -- their position, inasmuch as I
25 already have a full-time job and don't have much

34

1 additional effort -- or time, you know, to devote to
2 this.

3 The fact that a great deal of time was
4 consumed in essence managing the firm opinions of the
5 Board of Health, I felt that it was taking my energy
6 and that time away from other efforts that could have
7 been better expended to protect the public health.

8 Q. Understood. You referenced earlier the
9 board meeting of May 18th, 2020. I'd like to discuss
10 that for a moment.

11 So, that meeting on May 18, was that your
12 second board meeting that you attended?

13 A. Yes. Well, I'm sorry, Zach. That was the
14 second regularly scheduled board meeting that I
15 attended.

16 Q. And that board meeting on May 18 was held
17 remotely via Zoom?

18 A. Correct.

19 Q. Did you appear via Zoom?

20 A. I was present on audio, not on video.

21 Q. But you could see some people via video, or
22 you were just on your telephone?

23 A. No. I was on my computer. Actually, Zach,
24 I remember the first one was only done by telephone.

25 I believe the second one was done by Zoom.

35

1 But there have been so many Zoom meetings,
2 that's my current recollection. But, yes, I was on my
3 computer.

4 Q. So, could you describe what you remember of
5 that May 18th, 2020 board meeting by Zoom?

6 A. I believe I already mentioned two motions
7 that I recall from that meeting.

8 The other thing that was most striking to me
9 was when one of the Douglas County Commissioners, it
10 seemed to me out of nowhere, it was not on the agenda,
11 he asked the Chairwoman if he could present a proposal
12 for me as the Health Officer to sign.

13 He described it as a document which included
14 eight points, all of which would be easy to verify and
15 should be easy for me to sign.

16 Q. Just to interject, who was this that was
17 speaking?

18 A. Marc Straub.

19 Q. Thank you. Please continue.

20 A. This took me completely aback. I had no
21 idea what this was about, if this was normal activity.
22 Again, I was new in my role, four weeks. This was only
23 to --

24 Well, I had had very limited interactions
25 with the board members up until this point.

36

1 I will say my initial concern was that they
2 were interested in better understanding my personal
3 view of our capacity to further open the economy and
4 how that would affect our healthcare system.

5 And it felt awkward, it felt extremely
6 awkward to be asked by elected officials while I was
7 essentially brand-new in my role in a public meeting to
8 sign a document which I had not been -- which had not
9 been brought to my attention prior to the public
10 meeting, had in no way been reviewed with me or my
11 opinions asked about it prior to the public meeting.

12 So, I felt quite uncomfortable in that
13 moment. I remained silent. Several questions were
14 asked. I do not recall by whom. What was this for?
15 What was it about? Why would the Health Officer need
16 to sign it?

17 What I recall was Mr. Straub stating
18 that the Douglas County Commissioners wanted this
19 statement to allow them to review all options at their
20 disposal.

21 Eventually somebody said, "Well, what does
22 Malcolm think about this?"

23 And I said, "Well" --

24 I'm sorry. And he read, I believe he read
25 the eight points to the meeting. Several of them did

37

1 not make sense to me. Again, it seemed odd to me to
2 bring forward a statement with eight points already
3 laid out.

4 Again, in my mind I thought he was -- or the
5 perhaps Douglas County Commissioners, or at least his
6 constituency, were interested to know what my position
7 was on this.

8 I felt I had been fully transparent about my
9 position prior to this meeting, and was happy to
10 discuss my position should I be asked.

11 But instead they came forth with these eight
12 individual statements.

13 I told Mr. Straub that I would be happy to
14 review the document, and after review, I would offer my
15 opinion as to whether it was something I could sign.

16 He sounded satisfied with that. And we
17 proceeded after that.

18 Again, it was such an unusual situation and
19 directed most specifically at me in my new role in a
20 public forum that that is most of what I recall of that
21 meeting. It was for me the most emotionally ladened
22 portion of that meeting.

23 Q. Why do you indicate emotionally ladened?

24 A. Well, as I have described, I was new in my
25 role. I did feel an obligation to the constituency of

1 our Health District to serve them well, to appear
2 professional and helpful.

3 I certainly did not want to appear
4 obstreperous or defensive.

5 I will share, I of course felt defensive.

6 I feel it would have been more appropriate
7 with a person in my professional capacity who has
8 stepped up in the midst of a pandemic to communicate
9 with me prior to the board meeting about such a
10 document, to let me review it and provide my opinion as
11 to its merits and whether I could sign it.

12 As I mentioned, that did not happen.

13 So, I think the emotions I had were surprise
14 and frustration and concern. And "confusion" is the
15 wrong word, but sort of a question of, you know, where
16 on earth is this going and am I about to walk into a
17 mine field?

18 I will share with you that I have never
19 served before in any type of a public capacity, outside
20 of the Chief of Staff of the local hospital, which is
21 still in a professional capacity. I have rarely
22 been -- rarely spoken at such public forums. Certainly
23 not by Zoom.

24 I will share I think all of this has been
25 compromised by Zoom. I think if I had been sitting

39

1 it's an eight point document.

2 If you would take a moment, please, read
3 those eight points silently to yourself and let me know
4 once you have finished.

5 (Pause in the proceedings).

6 A. Finished.

7 Q. Okay. So, is this attached document on page
8 202 of Exhibit 2, is this consistent with your
9 recollection of what Mr. Straub read aloud during the
10 Zoom meeting?

11 A. Yes.

12 Q. Okay. So, at the time of this Zoom meeting
13 were you aware that Mr. Straub was contemplating
14 becoming a plaintiff in a lawsuit against the
15 Governor?

16 A. No.

17 Q. Did Mr. Straub say anything about a
18 potential lawsuit or any of the pending lawsuits
19 relating to the Stay Home - Stay Healthy proclamation?

20 A. He did not mention a lawsuit. He did
21 mention that the Douglas County Board of Commissioners,
22 I believe that's what the BOCC stands for, wanted
23 to use it essentially to evaluate what options they
24 had.

25 Q. Did he mention what options specifically the

42

1 County Commissioners of Douglas County were
2 contemplating?

3 A. He did not.

4 Q. Also at this time, May 18, were you aware
5 that board member Dan Sutton was also contemplating
6 becoming a party to a lawsuit to challenge the
7 proclamation?

8 A. I was not aware of that, no.

9 Q. Were you aware on May 18th that Ruth Esparza
10 was contemplating becoming a party to a pending
11 lawsuit, challenging the Governor's Stay Home - Stay
12 Healthy order?

13 A. No.

14 Q. So, at that meeting none of those three
15 board members said anything about a potential lawsuit
16 or challenging or contesting the Governor's Stay Home -
17 Stay Healthy order?

18 A. That is correct.

19 Q. Do you think they should have disclosed that
20 to you?

21 A. I feel it would have been -- Well, I'm going
22 to back up again. I have ignorance about public
23 meetings.

24 I am now aware that as a public officer, as
25 soon as I sign a document and return it to an elected

43

1 official, it becomes a public document. I was not
2 aware of that on May 18th.

3 When I look at how this document was
4 composed, in light of the fact that I am now aware of
5 the pending lawsuit, and having read through at least
6 one of the two pending lawsuits, it is clear to me that
7 this document had been created prior to the meeting
8 specifically to support a future lawsuit, as much as
9 the eight points parallel the points which are made in
10 the lawsuit.

11 That would also explain the unusual
12 presentation of eight individual points, and would also
13 explain why they referred to an influenza -- a document
14 related to an influenza pandemic which to my initial
15 read made absolutely no sense, since this is not an
16 influenza pandemic, but that plan and a rationale
17 regarding how it could potentially at least in a
18 dictionary relate to COVID-19.

19 So, in retrospect, if our team is to work
20 closely together in the future, yes, it would have been
21 appropriate for them to share with me that this
22 document was being developed to support a lawsuit.

23 Q. Had they shared that, would you have reacted
24 differently?

25 A. Again, my understanding that this document

44

1 was going to be used by the elected officials in their
2 elected capacities as the Douglas County Board of
3 Commissioners, I felt as a public now person in my
4 public role I was willing to support them in those
5 efforts.

6 I think the -- Well, will you repeat your
7 question again, Zach?

8 Q. My question is, had you known at the time,
9 on May 18th, that the eight point document was being
10 solicited or requested for use in a lawsuit by private
11 individuals against the Governor's stay at home order,
12 had you known that, how would you have reacted to the
13 request?

14 A. I think that's an important point you're
15 making.

16 At no time was it intimated in any way that
17 this might be used by private individuals. At all
18 times it was represented to me as in their public
19 roles.

20 I believe if I was aware that this document
21 was to be used in a lawsuit, I would have consulted
22 counsel prior to signing the document.

23 MR. JONES: So, I think this would
24 probably be a good time to take a break, for water, use
25 the restroom. I know your time is valuable so I don't

45

1 Sub-Exhibit B on page 63 --

2 A. Yes.

3 Q. -- of Exhibit 3. So this is an e-mail from
4 you to Mr. Straub on, dated May 18, 2020 at 4:34 p.m.
5 Is that right?

6 A. Yes.

7 Q. And this is in response to Mr. Straub's
8 e-mail at 3:48 p.m., which is on page 64, and we also
9 discussed it in Exhibit 2, in which he attached the
10 eight point document that he says the Douglas Board of
11 County Commissioners requested you to sign.

12 Is that right?

13 A. Yes.

14 Q. Okay. So, in this e-mail that you sent at
15 4:34 p.m., you wrote, and just follow along while I
16 read aloud, "Please provide some clarification:

17 "#2 - I am unaware of a plan for dealing
18 with endemic influenza, and unclear how that relates at
19 all to COVID-19. Can you explain how #2 adds strength
20 to the document?"

21 Did I read that right?

22 A. Yes.

23 Q. So, what did you mean that you were unclear
24 how that relates at all to COVID-19?

25 A. At that time I was unaware that the Health

48

1 District had a Pandemic Influenza Plan. I also
2 couldn't imagine how it was important that we had such
3 a plan since COVID-19 is not influenza.

4 From a medical perspective, they are
5 extremely different. Extremely? They are very
6 different.

7 And again, my impression at the time was
8 that he was trying to build a case regarding my
9 impression of our local capacity to tolerate further
10 opening the economy, and I couldn't understand how
11 mentioning that we had a Pandemic Influenza Plan would
12 be helpful in that regard.

13 Q. When you say influenza and COVID-19 are
14 very different from a medical perspective, what do you
15 mean?

16 A. Influenza, at least in the strains we were
17 most accustomed to, is well-known to us, we now have
18 vaccinations against it. We understand its
19 transmission well.

20 COVID-19, even though it's an old virus,
21 this novel form of the coronavirus is very poorly
22 understood to us. We do not understand -- we did not
23 at that time, bit by bit we are learning more, but we
24 essentially do not understand well how it is
25 transmitted.

1 There are no immunizations available to us.

2 Certainly both our viral infections, both as
3 far as we knew at that time were transmitted primarily
4 in a respiratory route via droplets.

5 It appeared at that time and still that
6 COVID-19 is dramatically more infectious. I've seen
7 reports between three and 12 times more infectious.

8 I am not aware that typical influenza
9 strains have a significant asymptomatic transmission or
10 significant portion of the population who are
11 asymptomatic throughout.

12 I would say that we haven't studied that.
13 It could be true. But since we have a very different
14 approach to influenza, we have not needed to study that
15 to date.

16 So, again, to my medical mind they are very
17 different viruses which create a very different
18 infection, and especially once people get very sick in
19 the hospital, it's an entirely different infection.

20 Q. Why do you say it's an entirely different
21 infection once they're sick in the hospital?

22 A. COVID-19 in a small subset of patients,
23 typically the elderly and medically frail, appears to
24 cause a massive immune response, and it is that immune
25 response that in essence causes multisystem organ

50

1 failure.

2 I have never heard of that previously with
3 viral infections. I have certainly never heard of it
4 related to influenza.

5 In my career, I have cared for hundreds and
6 hundreds of individuals with influenza. Within the
7 hospital I have certainly cared for dozens of elderly
8 sick people with influenza.

9 And I have never cared for a patient with
10 influenza who has had an illness course similar to what
11 I have read about with COVID-19.

12 Q. Thank you, Doctor. When you say "massive
13 immune response," are you referring to a cytokine
14 storm?

15 A. Yes.

16 Q. Have cytokine storms been observed in
17 COVID-19 patients who are not medically frail and not
18 elderly?

19 A. I believe that has occurred. I have not
20 attempted to keep up with that particular literature.

21 Q. Okay. So, you mentioned that at the time
22 you were not aware of the Health District's Pandemic
23 Influenza Plan.

24 Is that right?

25 A. Correct.

1 Q. Are you now aware of it?

2 A. I'm aware that it exists, yes.

3 Q. Have you familiarized yourself with it?

4 A. No.

5 Q. Okay. Returning to your e-mail at 4:34
6 p.m., this Sub-Exhibit B in Exhibit 3 --

7 A. Yes.

8 Q. -- I'm going to continue reading. Just read
9 along silently as I read aloud.

10 "#6 - Would you please clarify what you mean
11 by 'our pandemic plan'? I have not seen a written
12 pandemic plan? Could you send it to me?"

13 Did I read that correctly?

14 A. Yes.

15 Q. Did Mr. Straub eventually send you the
16 pandemic plan -- the Influenza Pandemic Plan?

17 A. Yes.

18 Q. Okay. Continuing with this e-mail, number
19 8, just continue to read along silently while I read
20 aloud.

21 "#8 - I think what you are looking for is a
22 statement that right now, from a health system
23 standpoint, we have plenty of capacity to experiment
24 with various levels of/types of reopening. I agree
25 with that. To say 'we are prepared for and capable of

52

1 know, that our healthcare system could accommodate
2 them, because, again, that's just -- it's too much.
3 It's too broad, too expansive.

4 Q. Thank you, Doctor. So, the next few
5 sentences of your e-mail, this is at the top of page 64
6 of Exhibit 3, you write, "I actually do NOT," capital
7 NOT, "feel comfortable that I fully understand the
8 present health threat. I am learning more about it
9 every day. It is the 'tip of the iceberg' analogy. I
10 have no way to assess (today) how much of the iceberg I
11 can see."

12 What did you mean by the tip of the iceberg
13 analogy?

14 A. Well, I think all of us are probably
15 familiar with that analogy.

16 I have made in many of the educational talks
17 and meetings I have had with local health care
18 officials and business members and on the local radio
19 that the COVID infection within our community, we can
20 only see the tip of that iceberg, and that is made
21 apparent to us through testing.

22 We can see the number of people who have
23 tested positive. We cannot easily see all of the rest
24 of the population who's carrying the virus and
25 contagion within the population.

1 So, I am describing that as the portion of
2 the iceberg which is under water and invisible to us.

3 So, similarly, even though we can see the
4 current health impacts and the way they are currently
5 impacting our healthcare system, we are not fully aware
6 of the burden of disease within our jurisdiction and
7 just how it could potentially impact our healthcare
8 system.

9 Q. Are you familiar with the term super-
10 spreader?

11 A. Yes.

12 Q. What does it mean to you?

13 A. To my mind a super-spreader would be an
14 individual who manages to transmit the virus to a
15 number of other individuals far above the standard R
16 value.

17 So, typically the examples I'm aware of
18 would be an individual who attends a choir practice
19 where there are 60 odd individuals present, who one of
20 whom is present and two hours later I believe 50 odd
21 are positive.

22 So, in a closed room while singing for
23 several hours, one individual can spread the virus
24 broadly to multiple other individuals.

25 I believe that is what's meant by the term

55

1 super-spreader.

2 Q. And does part of the tip of the iceberg
3 analogy encompass that potential where despite what you
4 think you know at a given time, that everything can
5 sort of turn on a dime in terms of the response to the
6 virus, and based on one or maybe even two super-
7 spreader events, that can change the entire trajectory
8 of the public health conditions and response needed?

9 Is that -- Are you in agreement with that?

10 A. Yes. I am mostly in agreement with, that
11 things can turn on a dime, that we can rapidly
12 encounter things that we've never seen before and we
13 need to cope with.

14 A super-spreader would be an example of
15 that, although that was not -- that specific example
16 was not in my mind as I wrote this e-mail.

17 Q. Understood. Turning to sub-Exhibit C, which
18 is before Exhibit B on page 63 of Exhibit 3. Let me
19 know when you see where sub-Exhibit C is.

20 A. I'm with you. Yes.

21 Q. Thank you. So, Mr. Straub responds to
22 you, "Thank you, Dr. Butler. I've attached the CDHD
23 Pandemic Flu Plan that originated - as I understand -
24 as a result of legislation in 2006."

25 Do you see that?

56

1 the pandemic plan.

2 He did that.

3 Thereafter, again, because I felt he was
4 interested to know my personal position, I created a
5 statement that outlined my personal position, and I
6 sent that to him, hoping that it would meet the
7 need.

8 Again, the eight points felt very awkward.
9 I could not understand again how that would be as
10 helpful as having my narrative. So I provided that to
11 him.

12 To my surprise he responded, "Thank you. I
13 appreciate that, and would you still sign the eight
14 point plan?"

15 And, again, I did not know this had been
16 built specifically to support a lawsuit. Now I am
17 aware that that is the case, or it certainly has
18 appeared to me that that is the case. And it appears
19 to me that that was the reason why he was not
20 interested in my actual narrative.

21 So, I again, hoping to please the
22 Commissioners who are now my new supervisors in this
23 role, I went through and edited the eight point
24 document in a way that I felt I could sign. I did --

25 I sent it back to him. He looked at it. He

59

1 said, "That looks fine."

2 I said, "Do you want it on letterhead or
3 signature or what?"

4 He said, "Fine, on letterhead, with a
5 digital signature."

6 And I provided that back to him.

7 I do recall that there seemed to be some
8 time pressure. Again, to my mind that didn't make good
9 sense. He wanted this I believe by Tuesday or
10 Wednesday.

11 One of the issues I had with the pandemic
12 plan that he sent me was that in total it was over 300
13 pages long. I did not feel I could adequately review
14 it in 48 hours.

15 But I do remember being curious as to the
16 time pressure that was involved.

17 Nonetheless, I was hoping to be as
18 forthright, transparent and helpful as possible. And
19 so we worked on and I finally signed the final product
20 that was provided to him.

21 Q. Okay. So, I'll represent to you that the
22 lawsuit to which Mr. Straub was the plaintiff, Sutton
23 vs. Inslee in Douglas County, was filed on May 22nd,
24 2020.

25 Knowing that, does that make more sense to

60

1 you now as to the time constraints that were apparently
2 being brought to bear?

3 A. Yes, absolutely.

4 Q. Let's turn to Sub-Exhibit A of Exhibit 3.

5 A. On what page?

6 MR. ZIMMERMAN: 62.

7 Q. (BY MR. JONES:) It's on page 62.

8 A. Thank you.

9 Q. So, what is this document, sub-Exhibit A?

10 A. This is the final product of the eight point
11 plan that I returned to Mr. Straub on my Columbia
12 Valley Community Health letterhead with my digital
13 signature.

14 Q. Okay. I'd like to just go over some of
15 these points in here.

16 Point number 2 on page 62, sub-Exhibit A,
17 says "I am aware that, pursuant to Chapter 70.26 RCW,
18 the Chelan-Douglas Health District developed a plan for
19 dealing with pandemic influenza in 2008.

20 Do you see that?

21 A. Yes.

22 Q. And what was that statement based on?

23 A. Again, I had been presented an eight point
24 plan. The second point of that original -- plan?
25 Sorry. Document.

61

1 The second point of that original document
2 referenced this Pandemic Flu Plan. I had been made
3 aware that it existed, and Mr. Straub appeared to want
4 this in the document.

5 Again, it was unclear to me why it was
6 helpful. But I was willing to provide it as it is a
7 true and correct statement.

8 Q. Okay. When you say "it is a true and
9 correct statement," was your statement based on
10 anything other than the information that Mr. Straub had
11 provided?

12 A. At some point I did confirm with Barry
13 Kling, the administrator of our Health District, that
14 the Health District had created an Influenza Pandemic
15 Plan. It was a brief, less than one minute
16 conversation and in a much longer conversation, and he
17 confirmed it. I do not recall the date of that
18 conversation.

19 But there was that conversation, and the
20 fact that I had the document in hand that made that a
21 true and correct statement.

22 Q. Understood. If you look at point number 6
23 where you raise, "Based on current knowledge, we do not
24 anticipate a shortage of hospital or other health care
25 resources to deal with the COVID-19 pandemic."

62

1 Q. I'm talking about the second -- I'm talking
2 about the second proposal.

3 A. Yes. If the second proposal is approved,
4 then I agree with your statement, it does allow for a
5 degree of tailoring, yes.

6 Q. So, in going back to this point 7 where you
7 say "our office would impose fewer restrictions on
8 residents within the boundaries of the Chelan-Douglas
9 Health District than are currently imposed by the
10 Governor's proclamations," is that comparison to what
11 the current status quo is for Chelan and Douglas
12 Counties, or to what the conditions would be if the
13 variance proposal is accepted?

14 A. I'm sorry, I do not recall the date of the
15 initial variance proposal being submitted.

16 When I constructed this document, it was
17 meant to mean that there would be fewer restrictions
18 than were currently in place at the time I constructed
19 it.

20 Q. Understood. So, in a world, hypothetically,
21 if the current pending Health District variance
22 proposal is accepted, would that represent what the
23 Health District would do, kind of left to its own
24 devices?

25 A. Zach, I don't think I can answer that with a

67

1 yes or a no. I would say the current variance
2 proposal, we were provided a fairly strict template to
3 follow in completing that. And we were provided fairly
4 specific examples that we might choose from.

5 I think it was -- It's very reasonable the
6 way it was presented to us. And I think the examples
7 were quite reasonable.

8 Had it not been presented in that way, I
9 do not think we would have returned it written as we
10 did.

11 For example, it says things like, you know,
12 certain businesses will be allowed at 25 percent
13 occupancy.

14 We probably would not have used that
15 parameter in our document.

16 It would have been largely similar, yes. It
17 would not have been just the same, no.

18 Q. Understood. Well, let me change the
19 hypothetical slightly. Let's say the variance proposal
20 is adopted, and then the Governor's proclamation is
21 lifted.

22 Can you identify a specific change that the
23 Health District would adopt in its own reopening plan,
24 compared to what the variance proposal reflects?

25 A. Well, there's a lot of hypotheticals here,

68

1 Zach.

2 Q. Understood.

3 A. And let's just all agree that we're talking
4 in hypotheticals here, and I hope they are valuable to
5 you in some way.

6 If I was allowed to make changes that I felt
7 were best -- would best fit our community, I would not
8 have allowed large box stores such as Target or Costco
9 to remain open, selling all of their wears, simply
10 because they also sold groceries, which are considered
11 essential.

12 That has put a huge volume of the population
13 inside those constrained spaces, and has not allowed
14 other retailers of other materials sold by Target and
15 Costco to also be open to the public.

16 That is overtly unfair. And that I think
17 has caused a great deal of -- It has made it difficult
18 for the population to keep itself safe by embracing the
19 Governor's proclamation.

20 I feel that if people saw that it was more
21 fairly imposed, and especially enforced, there would be
22 much greater acceptance.

23 And unfortunately, we're left with a lot of
24 anger and backlash to the point where people aren't
25 willing to even follow what I think are medically very

69

1 easy and justifiable precautions, such as wearing a
2 mask, because they're trying to make an act of civil
3 disobedience to their own peril.

4 Q. Would you say that the Stay Home - Stay
5 Healthy proclamation has been widely complied with in
6 Chelan and Douglas County?

7 A. "Widely" is a vague term. But I would say
8 if by widely, you mean more than half the population, I
9 would say yes.

10 Q. Thank you, Doctor. Sir, I'd like you to
11 turn now to what's tab R, and I hear a little bit of
12 background noise. I'm not sure if one of the
13 participants isn't on mute. But I do hear some strange
14 background noise. It looks like everyone is. But I
15 don't know what it is.

16 A. I am going to make sure -- No. It says
17 telephone. Can you hear me still?

18 Q. No, I can't hear you.

19 A. Okay. So, tab R will be Exhibit 4.

20 MR. ZIMMERMAN: Page?

21 MR. JONES: Page 204, the pages begin
22 203 is where the exhibit tab is.

23 THE WITNESS: Tab R is Exhibit 4, page
24 203. So labeled.

25 (Deposition Exhibit Number 4 was

70

1 marked for identification).

2 Q. (BY MR. JONES:) Okay. So, Exhibit 4, which
3 you have in front of you, is an e-mail from you to Mr.
4 Straub on May 19th at 5:03 p.m.

5 Please take a look at this e-mail at the top
6 there and let me know once you have finished reviewing
7 it.

8 (Pause in the proceedings).

9 A. All right.

10 Q. So, this e-mail is in the same e-mail thread
11 that we looked at in Exhibit 2 and 3.

12 Correct?

13 A. Yes.

14 Q. But this e-mail from you and its attachment
15 is not contained in either Exhibit 2 or Exhibit 3, is
16 it?

17 A. I believe the attachment is on page 207.

18 Q. Sorry. My question is, this e-mail from you
19 on May 19th --

20 A. Okay.

21 Q. -- is not contain in either the earlier
22 exhibits we were discussing, Exhibit 2 or Exhibit
23 3?

24 A. Okay. I believe that is correct. Yes.

25 Q. So, even though it was part of the same

71

1 e-mail thread, this was omitted from the e-mails in Mr.
2 Straub's declaration?

3 A. I know nothing about that. I don't know
4 what or why the prior exhibits were submitted or how
5 they got ordered in that way. But this does not look
6 like it is contained in anything we've looked at so
7 far.

8 Q. Understood. So, at the top of this e-mail
9 you write, "Marc, the attached is for your eyes only.
10 I would like to share with you my full and honest
11 approach to this pandemic. I am hoping that this will
12 fill the needs of those who you were representing when
13 you suggested the eight points for me to sign."

14 Why did you write that "I am hoping that
15 this will fill the needs of those who you were
16 representing when you suggested the eight points for me
17 to sign"?

18 A. Yes. As I've mentioned previously, it
19 was -- I mean, I was blindsided at the meeting by
20 the eight point document. I had no idea what it was
21 for.

22 Mr. Straub explained it was so that the
23 Douglas County Board of Commissioners could use it in
24 their future work.

25 My suspicion was that he was interested to

72

1 know my actual position on things. It was the only
2 reason I could think of.

3 Again, in retrospect, that's not what he was
4 after. The document appears to have been
5 pre-constructed specifically to support his lawsuit.

6 But when I wrote this e-mail I presented to
7 him my full narrative and my approach to where we were
8 at that moment.

9 Q. And in the next sentence you wrote "I am
10 trusting you not to take advantage of my being
11 vulnerable in this way with you."

12 What did you mean by being vulnerable?

13 A. Well, if you read the attachment, you will
14 see that I talk about a need to tolerate a certain
15 amount of mortality and morbidity.

16 And I think that taken out of context could
17 reflect very badly on me.

18 Within the context, I believe it is correct
19 and accurate. But it certainly, he could have taken
20 advantage of me by releasing portions of that document
21 out of context.

22 Q. Understood. So, at the bottom of the
23 e-mail you saw -- Oh. I'm sorry. Sorry. Before I get
24 there.

25 So, what was the paper that you attached?

73

1 Why did you attach the paper that you describe as a
2 physician paper?

3 A. Again, it was my belief that Marc and his
4 constituents were interested in discovering my view of
5 the pandemic and our capacity, our local capacity, to
6 further open the economy.

7 Q. And then you wrote, "If it weren't -- "If we
8 weren't in the midst of this craziness, I would invite
9 you out for a beer to discuss all of this more fully.
10 Without that, it would be best for the two of us to
11 discuss this by phone prior to involving others.

12 "You could call me tonight at 509," and then
13 your phone number's in there, and we have redacted your
14 phone number, just in case this document makes it into
15 a public court filing at any point.

16 So, did you ever speak with Mr. Straub by
17 telephone?

18 A. Yes.

19 Q. What did you discuss?

20 A. It's probably apparent just based on all
21 these documents when it happened, and I'm not
22 remembering right now.

23 But in essence I just wanted to talk through
24 with him the problems I had with the eight point
25 document.

74

1 And, so, yes, we did have a phone call.

2 He said, again, "I just need you to sign the
3 eight points."

4 And I went through and said, "It's going to
5 look kind of stupid, because none of these really make
6 good sense."

7 He said, "Just write whatever you can,
8 something that you can sign and support, and get it to
9 me. And if you can get it to me by Wednesday, that
10 will be great," or something to that effect.

11 Q. Okay. But you did speak with him on the
12 telephone?

13 A. Yes.

14 Q. And in your call on the phone did he provide
15 the additional context of the potential of the new
16 lawsuit being filed with him as a party?

17 A. Not at all. No. He actually had very good
18 opportunity to do exactly that, and he did not take
19 advantage of that opportunity.

20 Q. If you will turn to another exhibit, this is
21 tab P, it will be Exhibit 5.

22 A. Give me a page when you have it.

23 Q. 195.

24 A. Tab P, page 195 is Exhibit 5. So marked.

25 (Deposition Exhibit Number 5 was

76

1 Q. Okay. So, turning to point 2. In Exhibit 5
2 Mr. Straub wrote "Pursuant to Chapter 70.26 RCW, the
3 Chelan/Douglas Health District developed a plan for
4 dealing with pandemic influenza."

5 And then if you turn to Exhibit 3, point 2,
6 it is the same sentence, except you add "in 2008" at
7 the end.

8 Do you know why you did that?

9 A. I also added "I am aware that."

10 Q. Hmm. Thank you.

11 A. I did both of those, because later it
12 refers back to this document, and I wanted to clarify
13 that I had not written nor was I familiar with the
14 contents of the document, but I could attest that it
15 existed.

16 Also on the cover of the document the date
17 of creation is 2008.

18 And I put that in there honestly in an
19 effort to point out that this document is 12 years old.
20 Because, again, to my mind it makes no sense to be
21 referring back to this document. So, that was why.

22 Q. Understood. Point 3 you write -- Well,
23 excuse me.

24 Point 3 in Exhibit 5 Mr. Straub
25 wrote "COVID-19 is 'a new virus' that 'causes serious

79

1 present are adequate to deal with the expected number
2 of COVID-19 cases," and replaced it with, "our health
3 care resources at present are adequate to begin
4 reopening our economy."

5 Did I read that right?

6 A. Correct.

7 Q. Why did you do that?

8 A. To make it more specific and less expansive.

9 I can state that our health care resources at present
10 are adequate. But I have no foreknowledge of how many
11 COVID-19 cases should be expected into the future.

12 I felt the goal of this document was to
13 support reopening the economy, and I did and still do
14 feel that our health care resources are adequate to
15 begin reopening the economy.

16 I was uncomfortable attesting that our
17 health care resources at present are adequate to deal
18 with the expected number of COVID-19 cases, because I
19 do not know what the expected numbers are.

20 Q. Understood. Point 6 in Exhibit 5 Mr. Straub
21 wrote, "If our pandemic plan is followed, we do not
22 anticipate a shortage of hospital or other health care
23 resources to deal with the COVID-19 pandemic."

24 And you replaced that with, you deleted the
25 reference to the pandemic plan and said in Exhibit 3,

81

1 "based upon current knowledge, we do not anticipate a
2 shortage of hospital or other health care resources to
3 deal with the COVID-19 pandemic."

4 Is that right?

5 A. Yes.

6 Q. Why did you delete "If our pandemic plan is
7 followed" and replace it with "Based upon current
8 knowledge"?

9 A. Yeah. In short, not to look stupid. Again,
10 we've discussed this previously. I had no knowledge
11 and had not had the time to review the Influenza
12 Pandemic Plan, which is what I believe he was referring
13 to in number 6. And thus I couldn't comment on whether
14 following that plan would keep us safe.

15 But also it felt, from a medical standpoint,
16 it was ridiculous to refer to an Influenza Pandemic
17 Plan as we are confronting a novel virus and thus a
18 novel pandemic.

19 So, I tried to rephrase that in a way which
20 I could attest to, which was that based upon our
21 current knowledge we do not anticipate a shortage of
22 hospital or other health care resources to deal with
23 the COVID-19 pandemic.

24 Q. Thank you. And in point 7 you also deleted
25 Mr. Straub's reference to the pandemic plan, is that

1 right?

2 A. Yes.

3 Q. And did you do that for similar reasons?

4 A. Yes.

5 Q. Finally, in point 8 it appears as though you
6 deleted from Mr. Straub's version in Exhibit 5,
7 quote, "As well as any other present and anticipated
8 public health threats," and replaced it with in Exhibit
9 3, "as well as the additional threat posed by a phased
10 reopening of the economy."

11 Is that correct?

12 A. Yes.

13 Q. Why did you make that edit?

14 A. As we have discussed previously, number 8 to
15 my mind was too expansive.

16 In medicine we learn, always remember never
17 say "always" or "never." I'm sorry. Right. Always
18 remember never say "always" or "never."

19 And that just rings of that. Here we are,
20 "any other present or anticipated," that to me goes
21 against some of the maxims of medicine, and certainly
22 against the maxim of a pandemic.

23 So I removed that expansive statement and
24 replaced it with something I could support.

25 Again, I felt this was to support the

83

1 Douglas County Board of Commissioners' efforts to
2 reopen the economy, which is why I added that, because
3 I thought that was a threat that they were coping with,
4 "the additional threat posed by a phased reopening of
5 our economy.

6 Q. Thank you, Doctor. At some point did you
7 learn that your signed statement here in Exhibit 3,
8 Sub-Exhibit A, was used in multiple pending lawsuits?

9 A. Yes.

10 Q. Do you recall when you did learn that the
11 statement was used in various lawsuits?

12 A. Without looking at a calender, I couldn't
13 tell you the date. I can tell you it was at about nine
14 o'clock in the evening when one of my providers
15 messaged me with a concern that a Facebook post had
16 been sent to her. I believe it came out of Cashmere,
17 Washington.

18 And somebody had reported Chelan and Douglas
19 Counties had sued the Governor and that Dr. Butler was
20 supportive of this action.

21 And my provider understood that that would
22 not have been the case, and thus brought it to my
23 attention, because she was concerned that now on
24 social media I was being represented as supportive of
25 the lawsuit which had been brought against the

1 Governor.

2 Q. Understood. And what did you do when you
3 found that out?

4 A. I responded first to my provider. I thanked
5 her and said I would look into it.

6 Then of course everything became blindingly
7 apparent. You know, the way this was brought forward,
8 the eight points, the unwillingness to accept my
9 narrative.

10 Declarative statements in favor of going
11 back to the eight points made much more sense.

12 So, for whatever reason I thought that it
13 was Dan Sutton who had brought the initial proposal
14 forward.

15 Without going back to check any notes, I
16 e-mailed Dan and asked him if he had used my statement
17 in a personal lawsuit brought by him against the
18 Governor.

19 And he responded to me that he had never
20 handled that document.

21 And at that point I forget exactly what I
22 did. I must have looked back in some way and realized
23 that it was Marc Straub.

24 I know what. I went back and looked at the
25 e-mail exchange that we had had, realized that the

85

1 e-mail exchange was with Marc.

2 And then I sent the same e-mail to Marc,
3 asking him if he had used the declaration that I had
4 provided to him in his public capacity in a private
5 lawsuit that he had brought as an individual citizen
6 against the governor.

7 Q. And did he respond to that e-mail?

8 A. He did not respond directly to me. He
9 subsequently launched an e-mail to the entire Board of
10 Directors, which included a copy of that e-mail.

11 Q. This is the last document I want to bring up
12 with you. Sometimes those can be famous last words.
13 But this is tab ZZZ. This is the one that was loose.
14 So it was just printed earlier this morning. And it's
15 unnumbered. So, this will be Exhibit 6.

16 A. So marked.

17 (Deposition Exhibit Number 6 was
18 marked for identification).

19 Q. (BY MR. JONES:) Okay. Great. You're a pro
20 at this now, Dr. Butler.

21 Is this an e-mail that you were just
22 referring to, that you sent to Mr. Straub?

23 A. Yes.

24 Q. And the subject line of this e-mail is
25 "Deceit"?

86

1 A. Yes.

2 Q. Why did you chose that phrase for a subject
3 line?

4 A. It was my impression on that evening that
5 Marc, Mr. Straub, had had multiple opportunities to
6 clarify his intentions to me. That if we were
7 colleagues, working as a cohesive team for the good of
8 our local health jurisdiction, he would have approached
9 me individually, made clear the needs that he had for
10 his personal lawsuit, and asked me if I could support
11 it.

12 Instead, what appears to have happened was
13 that he deceived me into believing that he needed this
14 statement to support work that was being conducted by
15 the Douglas County Board of Commissioners. That is why
16 I used the word "deceit."

17 Q. Understood. Knowing what you know now, that
18 your statement was used in actually three lawsuits of
19 which I am aware, brought by private individuals
20 against the Governor's proclamation, would you, if you
21 could, retract the statement from the record?

22 A. I believe that the statement is true and
23 correct as signed.

24 What is difficult for me, number one, is I
25 am not accustomed to working with other individuals who

87

1 I feel are responsible for the public health of our
2 community in such an awkward, back-handed manner.

3 Again, we're in the age of COVID-19. I've
4 never met Mr. Straub. If we'd been at board meetings
5 together, it'd be different. Maybe nothing would have
6 happened the same way.

7 But in the current circumstances, what is
8 most upsetting and frustrating to me is the way that
9 the information was gained from me with clear
10 forethought and planning to be used in a way that was
11 not made clear to me.

12 Knowing what I know now, would I retract it?

13 I think I can probably get over the
14 disappointment I feel in the way that Mr. Straub
15 behaved.

16 But the public as I now understand is -- I'm
17 sorry, the document as I now understand is a public
18 document, and I stand by its contents.

19 So, no, although I feel I was a little bit
20 hoodwinked in getting it into those lawsuits, I don't
21 feel I have any grounds to retract it.

22 Q. Do you have any concerns that the statement
23 even as revised might be taken out of context to
24 suggest facts that aren't necessarily true?

25 A. I'm concerned that it reflects my support of

88

1 a lawsuit against the Governor and his proclamation,
2 and I would not participate knowingly in such a lawsuit
3 as a private citizen.

4 Q. Why?

5 A. Why?

6 Q. Why not?

7 A. I feel the Governor's actions have been
8 thoughtful and correct.

9 I am frustrated that they have not been
10 enforced fairly. And I feel that there unfortunately
11 has not been enough plasticities as the pandemic has
12 rolled out to allow us locally to be as nimble as we
13 would have wanted to be.

14 That said, I believe the governor acted with
15 the best information available to him, and I have no
16 concerns about the Governor's actions. So, I would not
17 have brought a lawsuit against him.

18 Q. Understood. I know I mentioned that your
19 statement had been used in at least three lawsuits
20 challenging the Governor's proclamations.

21 Have you, other than what we have reviewed
22 today, have you reviewed any of the pleadings, the
23 legal papers in those lawsuits or otherwise
24 familiarized yourself with the subject matter of those
25 lawsuits?

89

1 A. The only document I reviewed was Cuevas vs.
2 Jay Inslee, and I believe that was the Chelan County
3 document. That's the only one I have seen.

4 Q. And did you review the Complaint in that
5 lawsuit?

6 A. If they were -- If the Complaint was
7 included in the verbiage of the document, then, yes, I
8 would have reviewed it.

9 Q. Okay. Turning to Exhibit 3 again, your
10 statement in number 2 which says, it references Chapter
11 70.26 RCW.

12 Do you see that?

13 A. Can you tell me what page you are on, Zach?

14 Q. Oh, I am sorry. It's page 62 from Exhibit
15 3.

16 A. Yes.

17 Q. And do you see in point 2 there is a
18 reference to that chapter of the Washington -- the
19 Revised Code of Washington, 70.26?

20 A. I see that, yes.

21 Q. Did you ever review that chapter of the
22 code?

23 A. No.

24 Q. Okay. So, I'll represent to you that this
25 is a chapter of the Revised Code of Washington entitled

90

1 Pandemic Influenza Preparedness.

2 And I think it's a fair summary of this
3 lawsuit -- of several of the lawsuits in which
4 plaintiffs are challenging the proclamations, that
5 their view, plaintiffs' view, that this chapter
6 displaces or lessens the Governor's authority under his
7 executive, general executive powers to issue the
8 proclamation.

9 Does that make sense? Do you understand
10 that description?

11 A. Yes.

12 MR. DE WOLF: Excuse me. I'll object to
13 the form of the question as misstating the plaintiffs'
14 position, but you can go ahead and answer.

15 THE WITNESS: Yes.

16 Q. (BY MR. JONES:) Okay. So, setting aside
17 the legal questions, we don't expect you to interpret
18 the statute for us, setting aside the legal question,
19 in your medical and professional opinion, would a
20 county-by-county approach to the COVID-19 pandemic be a
21 reasonable and effective strategy for preventing or
22 slowing the spread of the disease?

23 A. No.

24 Q. Why not?

25 A. Over the last 27 years of my career I have

91

1 seen the local Public Health District emasculated, torn
2 apart. It's probably one-quarter of the size it used
3 to be.

4 There is just no conceivable way that our
5 local health jurisdiction could have the resources
6 required to understand or manage a pandemic like this.

7 I believe that the State Department of
8 Health does have access to those resources. It has
9 full-time prepared epidemiologists and public health
10 officers working closely with academic institutions on
11 modeling and guidance which is something that as a
12 family physician I couldn't begin to approximate.

13 So, there is no way that I would be prepared
14 at a local level to manage a county-by-county for my
15 two counties response without enormous support provided
16 by the State Department of Health.

17 MR. JONES: I think I may be done, but
18 I'd like to have five minutes to review my material.
19 So, I realize I've gone a little bit longer than I
20 said, but if you will just indulge me for five more
21 minutes to go over my notes.

22 THE WITNESS: Could we take a time-out?

23 MR. JONES: Yes. Thank you. We will go
24 off the record now.

25 (Short recess).

1 MR. JONES: Okay. Let's go back on the
2 record.

3 Q. Dr. Butler, I have just one or a few more
4 questions.

5 We talked a bit about the Health District's
6 Pandemic Influenza Plan.

7 Do you recall that?

8 A. Yes.

9 Q. I think I know what the answer to this next
10 question's going to be, but I have to ask it anyway.

11 Has the Health District Pandemic Influenza
12 Plan governed the Health District's response to
13 COVID-19?

14 A. My understanding is that prior to assuming
15 my current position, that plan was used to set up the
16 initial phases of our response.

17 During my time in this role I have not seen
18 it referred to.

19 Q. And what was that understanding based off
20 of?

21 A. I believe a discussion I had with Mr. Kling,
22 and he stated that the Pandemic Flu Plan had been very
23 helpful since they were beginning to school up and
24 decide how they were going to structure themselves to
25 confront this pandemic.

1 STATE OF WASHINGTON)
) ss.
 2 County of Spokane)
 3

4 I, William J. Bridges, do hereby certify that
 5 at the time and place heretofore mentioned in the
 6 caption of the foregoing matter, I was a Certified
 7 Shorthand Reporter for the State of Washington, and
 8 pursuant to RCW 5.28.010, am authorized to administer
 9 oaths and affirmations in and for the State of
 10 Washington; that at said time and place I reported in
 11 stenotype all testimony adduced and proceedings had in
 12 the foregoing matter; that thereafter my notes were
 13 reduced to typewriting and that the foregoing
 14 transcript consisting of 94 typewritten pages is a true
 15 and correct transcript of all such testimony adduced
 16 and proceedings had and of the whole thereof.

17 I further certify that I am herewith securely
 18 sealing the original deposition transcript and promptly
 19 delivering the same to Attorney Zachary Pekelis Jones.

20 Witness my hand at Spokane, Washington, on
 21 this _____ day of June, 2020.
 22

23 _____
 24 William J. Bridges
 25 CSR NO. 2421
 Certified Shorthand Reporter
 My commission expires: 11-1-20

1 CERTIFICATE OF WITNESS

2

3 STATE OF WASHINGTON)

4 COUNTY OF CHELAN)

5

6 I, MALCOLM D. BUTLER, declare under penalty of

7 perjury under the laws of the State of Washington, that

8 I am the witness named in the foregoing deposition and

9 that I have read the questions and answers thereon as

10 contained in the foregoing deposition, consisting of

11 pages 6 through 94; that the answers are true and

12 correct as given by me at the time of taking the

13 deposition, except as indicated on the correction

14 sheet.

15

16

17 _____

18 MALCOLM D. BUTLER

19

20 Executed on the _____ day of _____,

21 2020, at _____, _____.

22 (City) (State)

23

24 JOSE LUIS CUEVAS, et al vs. JAY INSLEE

25 June 8, 2020

Exhibit F

From: [Barry Kling](#)
To: ["brian.burnett@co.chelan.wa.us"](mailto:brian.burnett@co.chelan.wa.us)
Subject: FW: Proposed Reopening in New Proposal

Brian here's a comment I shared with BOH a while ago about the pan flu plan. I think there is a misconception that it should govern our response. Even for pan flu, which COVID is NOT, a plan is meant only as guidance. As a famous general once said, no plan long survives significant contact with the enemy. And in the process of developing pan flu plans, every single official involved – Federal, state and local – repeatedly emphasized that a plan can only be a rough guide and must be modified as needed in the fact of actual circumstances. So I am a bit mystified by the apparent fixation on a document that was known from the beginning to require flexibility.

From: Barry Kling

Sent: Thursday, June 4, 2020 11:52 AM

To: Ruth Esparza <resparza@wenatcheewa.gov>; Sharon Waters <yomama21@frontier.com>

Cc: Board of Health <boardofhealth@cdhd.wa.gov>; Marc Straub <mstraub@co.douglas.wa.us>; Peter Rutherford <peter.rutherford@confluencehealth.org>; Diane Blake <diane@cascaedemical.org>; Malcolm Butler <mbutler@cvch.org>; Shiloh Burgess <burgess.shiloh@gmail.com>; Brian Burnett <brian.burnett@co.chelan.wa.us>; Frank Kuntz <FKuntz@WenatcheeWA.Gov>; Jerrilea Crawford <jcrawford@eastwenatcheewa.gov>; West Mathison <west.mathison@stemilt.com>

Subject: RE: Proposed Reopening in New Proposal

Ruth I am not sure why there has been so much focus on a pandemic plan designed years ago for a different organism. This plan did help us get started on our COVID response by helping us review the major aspects of a pandemic response for an infectious disease, but the actual pattern of the COVID pandemic has differed from typical flu epidemics, in at least two ways. The initial peak has not been as sharp and the decline not as rapid as one usually sees with flu. That has meant social distancing lasting longer than anticipated with flu in mind. Second, even the most conservative estimates suggest that COVIE-19 is about 13 times – that's 13 TIMES – more deadly than flu. So the idea that they are comparable and that a plan made for flu should be a rigid guide to our current measures does not really make sense. I am glad that our local outbreak is not as bad as it would have been without social distancing, or as bad as it has been in many other communities, but we are not out of the woods. Nationally we are seeing that the epidemic in more rural areas lags behind that in cities, and hot spots are starting to emerge. We don't yet know how bad they will be.

That said, I fully support the reopening we are proposing because social distancing simply cannot last forever and we do currently have a low level of severe infections, even though total numbers are relatively high compared with other counties. I think we have a good chance of getting somewhere on this with the great support we've received from the Board.

From: Ruth Esparza <REsparza@WenatcheeWA.Gov>

Sent: Thursday, June 4, 2020 11:29 AM

To: Sharon Waters <yomama21@frontier.com>

Cc: Barry Kling <barry.kling@cdhd.wa.gov>; Board of Health <boardofhealth@cdhd.wa.gov>; Marc Straub <mstraub@co.douglas.wa.us>; Peter Rutherford <peter.rutherford@confluencehealth.org>; Diane Blake <diane@cascaedemical.org>; Malcolm Butler <mbutler@cvch.org>; Shiloh Burgess <burgess.shiloh@gmail.com>; Brian Burnett <brian.burnett@co.chelan.wa.us>; Frank Kuntz <FKuntz@WenatcheeWA.Gov>; Jerrilea Crawford <jcrawford@eastwenatcheewa.gov>; West

Mathison <west.mathison@stemilt.com>

Subject: Re: Proposed Reopening in New Proposal

While I agree with the current plan proposal to the governor, I am wondering why we don't have a plan to execute the pandemic, at a local level, as we say we will do in our own CDHD PANDEMIC PLAN, pages 21-27?

Ruth

Sent from my iPad

On Jun 4, 2020, at 10:47 AM, "yomama21@frontier.com" <yomama21@frontier.com> wrote:

CAUTION: This email originated from outside of the City of Wenatchee. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Barry,

I agree with Marc.

I like the added comments...not sure they were just for us or will be sent along with the proposal.

Please thank the work group for their time and energy.

Stay safe,

Sharon

"Be the reason someone smiles today"

On Thursday, June 4, 2020, 09:32:44 AM PDT, Marc Straub (x6363)

<mstraub@co.douglas.wa.us> wrote:

Barry,

First, I would like to express my gratitude to you and the workgroup for your work in putting this together in short order—thank you.

In reviewing the information, I, too, would be supportive of the proposal being recommended by the workgroup, along with Kevin's recommendations added.

Again, thank you.

Kind Regards,

Marc S. Straub | County Commissioner - District 3

Douglas County

203 S. Rainier | P.O. Box 747, Waterville, WA 98858

Office: (509) 745-8537 | Cell: (509) 449-5097 | Email: mstraub@co.douglas.wa.us

www.douglascountywa.net

NOTICE: This communication and attachment(s) may be considered public information and subject to the provisions of the State of Washington Public Records Act.

From: Barry Kling [<mailto:barry.kling@cdhd.wa.gov>]

Sent: Wednesday, June 3, 2020 4:19 PM

To: Board of Health <boardofhealth@cdhd.wa.gov>

Cc: Peter Rutherford <peter.rutherford@confluencehealth.org>; Diane Blake <dianebl@cascademedical.org>; Malcolm Butler <mbutler@cvch.org>; Shiloh Burgess <burgess.shiloh@gmail.com>; Brian Burnett <Brian.Burnett@co.chelan.wa.us>; Frank Kuntz <fkuntz@wenatcheewa.gov>; Jerrilea Crawford <jcrawford@eastwenatcheewa.gov>; West Mathison <west.mathison@stemilt.com>

Subject: Proposed Reopening in New Proposal

[EXTERNAL MESSAGE]

Dear Board of Health:

I have attached a file that shows 3 different reopening proposals in parallel columns. One is the “intermediate” version suggested in the Governor’s document of 5/31/2020 (also attached) for counties not ready for Phase 2. Another is the Phase 2 list of allowed and prohibited activities. And the third is the proposal our workgroup has developed over the past few days. Because we want to be as close as possible to something BOH can endorse – and because BOH endorsement cannot happen without a list of the proposed measures – we want to get your feedback on this as soon as possible.

So please take a look and share any concerns or comments. What we do next will depend in part on whether the approach we have developed makes sense to board members, so we do need your comments. We have attempted to ask for significant reopening without going too far. It is interesting to note that our approach is almost identical to that submitted today by King County, after our proposal had already taken shape.

Our workgroup will be having a zoom conversation at 11AM tomorrow, the CDHD staff and the organizations represented on our workgroup are pulling together the necessary numbers and other information, and I will be working to pull it all together and draft a narrative making our case (with further input from workgroup members) tonight and tomorrow. We are hoping to have something coherent to share with you Thursday night or Friday morning.

Best –

Barry

~~~~~

Barry Kling, MSPH, Administrator

Chelan-Douglas Health District

200 Valley Mall Parkway

East Wenatchee, WA 98802

Office: 509-886-6480

Cell: 509-264-7045

---

This email may be subject to disclosure as a public record under the Public Records Act, RCW Chapter 42.56

# Exhibit G

**From:** Marc Straub (x6363)  
**To:** Malcolm Butler  
**Subject:** RE: BOH Packet for Monday, May 18, 2020  
**Date:** Wednesday, May 20, 2020 12:07:46 PM

---

Hello Dr. Butler,

Thank you for your response and consideration of the proposed statement draft that I provided. I know how very busy you are and I sincerely appreciate the time you carved out.

It goes without saying that I will respect your request that your attachment go no further than me. I appreciate your honesty and candor expressed in the attachment. I appreciate what appears clearly to me to be your recognition that a balance must be struck between protecting our citizens' health and well-being, and our economic and financial well-being during this pandemic. I couldn't agree more.

As I shared with Barry, it comes as no surprise that you were not familiar with the CDHD Pandemic Flu Plan, as you only assumed your new role weeks ago and, one can only imagine how busy you've been since the start of the COVID-19 pandemic.

Malcolm, it would never be my intent to take advantage of someone's vulnerability—that's not how I'm wired and not part of my character. That being said, as I mentioned in Monday's BOH meeting, and in my previous email, this request for a signed statement is being made as the Douglas BOCC is looking at all options for continuing to petition the governor to move forward in a sensible manner from the current Phase One constraints.

We're simply asking that—as the CDHD Medical Officer—you sign a statement that includes the following points to the extent you're comfortable. I completely understand, as you mentioned earlier, that you would need to redraft #8 (or any other point for that matter) to accurately express your perspective and comfort level—no problem.

1. I am the regional health officer for the Chelan-Douglas Health District.
2. Pursuant to Chapter 70.26 RCW, the Chelan-Douglas Health District developed a plan for dealing with pandemic influenza.
3. COVID-19 is "a new virus" that "causes serious illness, and then spreads easily from person to person."
4. I am working with other public health officials to minimize the spread of COVID-19 within the boundaries of the Chelan-Douglas Health District.
5. Although there was a threat in the early stages of the COVID-19 pandemic in Washington that hospitals would be overwhelmed with cases and that patients would be unable to obtain the medical care necessary to treat COVID-19, our health care resources at present are adequate to deal with the expected number of COVID-19 cases.
6. If our pandemic plan is followed, we do not anticipate a shortage of hospital or other health care resources to deal with the COVID-19 pandemic.
7. If our pandemic plan is followed, our office would impose fewer restrictions on residents within the boundaries of the Chelan-Douglas Health District than are currently imposed by the Governor's Proclamations.
8. My office, together with other public health officials, is prepared for and capable of dealing with the current threat to public health posed by COVID-19, as well as any other present and anticipated public health threats.

If you're agreeable to providing this document, it would be extremely helpful to have it today or early tomorrow.



Again, thank you, Malcolm—sincerely appreciated.

Kind Regards,

**Marc S. Straub | County Commissioner - District 3**

**Douglas County**

203 S. Rainier | P.O. Box 747, Waterville, WA 98858

Office: (509) 745-8537 | Cell: (509) 449-5097 | Email: [mstraub@co.douglas.wa.us](mailto:mstraub@co.douglas.wa.us)

[www.douglascountywa.net](http://www.douglascountywa.net)

*NOTICE: This communication and attachment(s) may be considered public information and subject to the provisions of the State of Washington Public Records Act.*

**From:** Malcolm Butler [<mailto:mbutler@cvch.org>]

**Sent:** Tuesday, May 19, 2020 5:04 PM

**To:** Marc Straub (x6363) <[mstraub@co.douglas.wa.us](mailto:mstraub@co.douglas.wa.us)>

**Subject:** RE: BOH Packet for Monday, May 18, 2020

[EXTERNAL MESSAGE]

---

Marc,

The attached is for your eyes only. I would like to share with you my full and honest approach to this pandemic. I am hoping that this will fill the needs of those who you were representing when you suggested the eight points for me to sign. I am trusting you not to take advantage of my being vulnerable in this way with you.

Dude, combined the two documents you sent me are over 300 pages. I need to read through those to best serve in my new role as Health Officer. Optimally I would have read them before the worst disaster in modern history hit, but alas, my other full time job has kept me busy. It will take me weeks to get through those.

If the position-paper I have attached is sufficient, even with some further clarification, to meet the need, then I can take the required time to read through the 300 pages.

If we weren't in the midst of this craziness, I would invite you out for a beer to discuss all of this more fully. Without that, it would be best for the two of us to discuss this by phone prior to involving others.

You could call me tonight at 509-██████████.

**Malcolm Butler**

**CVCH Chief Medical Officer**

(509) 662-6000 • [cvch.org](http://cvch.org) • #iHeartCVCH

**Connect:** [Facebook](#) • [Vimeo](#) • [Instagram](#)

Locations in Wenatchee, East Wenatchee & Chelan.

---

**From:** Marc Straub (x6363) <[mstraub@co.douglas.wa.us](mailto:mstraub@co.douglas.wa.us)>

**Sent:** Tuesday, May 19, 2020 2:52 PM

**To:** Malcolm Butler <[mbutler@cvch.org](mailto:mbutler@cvch.org)>

**Subject:** RE: BOH Packet for Monday, May 18, 2020

Good Morning Dr. Butler,

I wanted to follow-up with you to be certain you received my clarifications last evening. Thank you.

Kind Regards,

**Marc S. Straub | County Commissioner - District 3**

**Douglas County**

203 S. Rainier | P.O. Box 747, Waterville, WA 98858

Office: (509) 745-8537 | Cell: (509) 449-5097 | Email: [mstraub@co.douglas.wa.us](mailto:mstraub@co.douglas.wa.us)

[www.douglascountywa.net](http://www.douglascountywa.net)

*NOTICE: This communication and attachment(s) may be considered public information and subject to the provisions of the State of Washington Public Records Act.*

**From:** Malcolm Butler [\[mailto:mbutler@cvch.org\]](mailto:mbutler@cvch.org)

**Sent:** Monday, May 18, 2020 4:34 PM

**To:** Marc Straub (x6363) <[mstraub@co.douglas.wa.us](mailto:mstraub@co.douglas.wa.us)>

**Subject:** RE: BOH Packet for Monday, May 18, 2020

[EXTERNAL MESSAGE]

Please provide some clarification:

#2 – I am unaware of a plan for dealing with pandemic influenza, and unclear how that relates at all to COVID-19. Can you explain how #2 adds strength to the document?

#6 – Would you please clarify what you mean by “our pandemic plan”? I have not seen a written pandemic plan. Could you send it to me?

#8 – I think what you are looking for is a statement that right now, from a health system standpoint, we have plenty of capacity to experiment with various levels of / types of reopening. I agree with that. To say “we are prepared for and capable of dealing with the current threat to public health posed by COVID-19, as well as any other present and anticipated public health threats” feels a little expansive. I actually do NOT feel comfortable that I fully understand the present health threat. I am learning more about it every day. It is the “tip of the iceberg” analogy. I have no way to assess (today) how much of the iceberg I can see. Could you restate #8? Or would you like me to restate in a way I agree with?

**Malcolm Butler**

**CVCH Chief Medical Officer**

(509) 662-6000 • [cvch.org](http://cvch.org) • #iHeartCVCH

**Connect:** [Facebook](#) • [Vimeo](#) • [Instagram](#)

Locations in Wenatchee, East Wenatchee & Chelan.

**From:** Marc Straub (x6363) <[mstraub@co.douglas.wa.us](mailto:mstraub@co.douglas.wa.us)>

**Sent:** Monday, May 18, 2020 3:48 PM

**To:** Lorena Orozco <[Lorena.Orozco@cdhd.wa.gov](mailto:Lorena.Orozco@cdhd.wa.gov)>; Board of Health <[boardofhealth@cdhd.wa.gov](mailto:boardofhealth@cdhd.wa.gov)>; Francis Collins <[francis.collins@cdhd.wa.gov](mailto:francis.collins@cdhd.wa.gov)>; Malcolm Butler <[mbutler@cvch.org](mailto:mbutler@cvch.org)>

**Cc:** Tiana Rowland (x6360) <[trowland@co.douglas.wa.us](mailto:trowland@co.douglas.wa.us)>

**Subject:** RE: BOH Packet for Monday, May 18, 2020

Good Afternoon,

Per discussion, I've attached the document that outlines the eight points the Douglas BOCC would request that our Regional Health Officer prepare as a signed statement.

Kind Regards,

**Marc S. Straub | County Commissioner - District 3**

**Douglas County**

203 S. Rainier | P.O. Box 747, Waterville, WA 98858

Office: (509) 745-8537 | Cell: (509) 449-5097 | Email: [mstraub@co.douglas.wa.us](mailto:mstraub@co.douglas.wa.us)

[www.douglascountywa.net](http://www.douglascountywa.net)

*NOTICE: This communication and attachment(s) may be considered public information and subject to the provisions of the State of Washington Public Records Act.*

**From:** Lorena Orozco [<mailto:Lorena.Orozco@cdhd.wa.gov>]

**Sent:** Thursday, May 14, 2020 3:54 PM

**To:** Board of Health <[boardofhealth@cdhd.wa.gov](mailto:boardofhealth@cdhd.wa.gov)>; Francis Collins <[francis.collins@cdhd.wa.gov](mailto:francis.collins@cdhd.wa.gov)>; 'Malcolm Butler' <[m.butler@cvch.org](mailto:m.butler@cvch.org)>; Tiana Rowland (x6360) <[trowland@co.douglas.wa.us](mailto:trowland@co.douglas.wa.us)>

**Subject:** BOH Packet for Monday, May 18, 2020

**Importance:** High

[EXTERNAL MESSAGE]

---

Good afternoon,

Attached are the Board meeting documents for Monday, May 18, 2020. The meeting will begin at 3:00 p.m. via ZOOM conference call.

Please respond to this email as soon as possible to confirm if you will be able to participate via conference call. Thank you!

Have a great day!

*Lorena Orozco*

Chief Deputy Registrar/Fiscal Assistant  
Chelan-Douglas Health District  
200 Valley Mall Parkway  
E. Wenatchee, WA 98802  
Phone: (509)886-6416  
Fax: (509)886-6436

---

This email may be subject to disclosure as a public record under the Public Records Act, RCW Chapter 42.56

---

This email may be subject to disclosure as a public record under the Public Records Act, RCW Chapter 42.56

---

This email may be subject to disclosure as a public record under the Public Records Act, RCW Chapter 42.56

# Exhibit H



From: Malcolm Butler <[mbutler@cvch.org](mailto:mbutler@cvch.org)<<mailto:mbutler@cvch.org>>>  
Subject: Deceit  
Date: May 28, 2020 at 9:23:25 AM PDT  
To: Marc Straub <[mstraub@co.douglas.wa.us](mailto:mstraub@co.douglas.wa.us)<<mailto:mstraub@co.douglas.wa.us>>>  
Cc: Jill Thompson <[thompson.jilldaling@gmail.com](mailto:thompson.jilldaling@gmail.com)<<mailto:thompson.jilldaling@gmail.com>>>

Marc,

Did you use the statement I provided to you, in your public role as a member of the Chelan Douglas Board of Health, in a private law suite, without informing me and the board that you would use it to portray my endorsement of your private position, without my express permission?

Malcolm Butler  
CVCH Chief Medical Officer  
(509) 662-6000 • [cvch.org](http://cvch.org)<<https://www.cvch.org/>> • #iHeartCVCH

Connect: Facebook<<https://www.facebook.com/ColumbiaValleyCommunityHealth/>> •  
Vimeo<<https://www.vimeo.com/cvch>> • Instagram<<https://www.instagram.com/iheartcvch/>>  
Locations in Wenatchee, East Wenatchee & Chelan.



# Exhibit I



COVID-19 is an emerging, rapidly evolving situation.  
 Get the latest public health information from CDC: <https://www.coronavirus.gov> .  
 Get the latest research from NIH: <https://www.nih.gov/coronavirus>.  
 Find NCBI SARS-CoV-2 literature, sequence, and clinical content: <https://www.ncbi.nlm.nih.gov/sars-cov-2/>.

Journal List > Emerg Infect Dis > v.19(6); 2013 Jun > PMC3713824



[Emerg Infect Dis](#). 2013 Jun; 19(6): 879–885.

PMCID: PMC3713824

doi: [10.3201/eid1906.121478](https://doi.org/10.3201/eid1906.121478)

PMID: [23731839](https://pubmed.ncbi.nlm.nih.gov/23731839/)

## Pandemic Influenza Planning, United States, 1978–2008

[John Iskander](#),<sup>✉</sup> [Raymond A. Strikas](#), [Kathleen F. Gensheimer](#),<sup>1</sup> [Nancy J. Cox](#), and [Stephen C. Redd](#)

☐ Author information ☐ Copyright and License information [Disclaimer](#)

This article has been [cited by](#) other articles in PMC.

### Abstract

Go to: ☒

During the past century, 4 influenza pandemics occurred. After the emergence of a novel influenza virus of swine origin in 1976, national, state, and local US public health authorities began planning efforts to respond to future pandemics. Several events have since stimulated progress in public health emergency planning: the 1997 avian influenza A(H5N1) outbreak in Hong Kong, China; the 2001 anthrax attacks in the United States; the 2003 outbreak of severe acute respiratory syndrome; and the 2003 reemergence of influenza A(H5N1) virus infection in humans. We outline the evolution of US pandemic planning since the late 1970s, summarize planning accomplishments, and explain their ongoing importance. The public health community's response to the 2009 influenza A(H1N1)pdm09 pandemic demonstrated the value of planning and provided insights into improving future plans and response efforts. Preparedness planning will enhance the collective, multilevel response to future public health crises.

**Keywords:** pandemic influenza, influenza, public health preparedness, pandemic planning, viruses

### Historical Background

Go to: ☒

Influenza pandemics occur when an animal influenza virus to which humans have no or limited immunity acquires the ability, through genetic reassortment or mutation, to cause sustained human-to-human transmission leading to community-wide outbreaks (1). The existence of a pandemic is currently determined by the extent of disease spread, not by the lethality of the disease caused by the novel virus (2). During the twentieth century, influenza

### Formats:

Article | [PubReader](#) | [ePub \(beta\)](#) | [PDF \(414K\)](#) | [Citation](#)

### Share

[Facebook](#) [Twitter](#) [Google+](#)

### Save items

★ Add to Favorites

### Similar articles in PubMed

Pandemic planning and response in academic pediatric emergency dep: [Acad Emerg Med. 2013]

[The influenza, a growing pandemic that calls for all possible provisions [Bull Soc Pathol Exot. 2011]

The emergence of pandemic influenza viruses. [Protein Cell. 2010]

[Influenza A/H1N1 virus--old and new]. [Harefuah. 2009]

History of Swine influenza. [Curr Top Microbiol Immunol. 2013]

[See reviews...](#)

[See all...](#)

### Cited by other articles in PMC

Animal models for the risk assessment of viral pandemic pot [Laboratory Animal Research. 2020]

Influence of Community and Culture in the Ethical Allocation of Sca [Journal of Participatory Medic...]

Emerging infectious diseases: Focus on infection control issues for [American Journal of Infection ...]

Ethics for pandemics beyond influenza: Ebola, drug-resistant tu [Monash Bioethics Review. 2015]

Preparing intensive care for the next pandemic influenza [Critical Care. 2019]

[See all...](#)

### Links

[MedGen](#)

[PubMed](#)

[Taxonomy](#)

g Infect Dis  
Emerg Infect Dis  
Emerg Infect Dis  
Emerg Infect Dis

pandemics occurred in 1918, 1957, and 1968. The 1918 pandemic, known as the “Spanish flu” pandemic, was unique in that the highest number of deaths was among young, healthy persons. Excess mortality in the United States during the 1918 pandemic was estimated at 546,000 deaths (3). The pandemics in 1957 and 1968, although associated with death rates greater than those for seasonal influenza epidemics (3), were far less devastating than the 1918 pandemic.

Before 1976, public health planning for pandemics primarily occurred in response to detection of a novel influenza virus. This reactive mode continued despite the framework outlined in 1960 by US Surgeon General L.E. Burney for responding to the next pandemic. That framework involved recognition of the pandemic (i.e., surveillance), manufacture and distribution of vaccine, and identification of research needs (4). Large-scale infectious disease response planning may have been hampered by the tacit assumption that the government’s public health resources were better directed to other priorities.

In January 1976, a novel swine-origin influenza virus emerged among soldiers at Fort Dix, New Jersey (5); 1 soldier died, and an estimated 230 were infected. The emergence of influenza virus of swine origin at Fort Dix led to the decision to mount a national immunization program (6). The following events occurred subsequent to this decision: Congress funded vaccine production and liability indemnification of manufacturers, vaccine was produced, a mass immunization campaign commenced, and 45.65 million persons were vaccinated in the United States (7). Initial fears that the virus would cause a pandemic did not materialize: sustained transmission did not occur outside of Fort Dix. The vaccination campaign began in October 1976 and was halted in December because of initial reports of a rare association between the so-called “swine flu” vaccine and Guillain-Barré syndrome; the association was later confirmed (7). An influential policy review of the “swine flu affair” (i.e., the campaign to immunize the US population against a possible epidemic) identified several critical needs for future planning: 1) a more cautious approach to interpreting limited data and communicating risk to the public, 2) greater investment in research and preparedness, 3) clearer operational responsibilities within the federal government, 4) clear communication between planners at all levels of government, 5) strengthened local capacity for plan implementation, and 6) improved mechanisms for program evaluation (8).

In November 1977, separate from the Fort Dix outbreak, a strain of human influenza A(H1N1) virus reemerged in the former Soviet Union, northeastern China, and Hong Kong, China, even though the virus had not circulated since 1957. This strain primarily affected young persons, and caused mild illness (9). The virus was found to be closely related to a 1950 A(H1N1) strain but dissimilar to the 1957 strain, suggesting that this 1977 outbreak strain had been preserved since 1950 (9).

The confluence of fears of a possible pandemic in 1976 followed by the reemergence of a new strain of circulating seasonal influenza virus in 1977 led to focused pandemic planning efforts in the United States. The primary purpose of this article is to describe US pandemic planning during 1978–2008, just before the onset of the influenza A(H1N1)pdm09 pandemic in April 2009. We believe that understanding the historical and policy context within which the A(H1N1)pdm09 pandemic occurred is helpful in assessing the implications of pandemic planning for responses to future pandemics and for ongoing infectious disease preparedness efforts.

Recent Activity

Turn Off Clear

Pandemic Influenza Planning, United States, 1978–2008

See more...

Historical perspective--Emergence of influenza A (H1N1) viruses. [N Engl J Med. 2009]

Preparing for pandemic influenza: the need for enhanced surveillance. [Emerg Infect Dis. 1999]

Review Influenza pandemic preparedness. [Emerg Infect Dis. 2003]

Emerg Infect Dis

Emerg Infect Dis

Emerg Infect Dis

Eme

We conducted searches of the medical literature and key websites (e.g., [www.pandemicflu.gov](http://www.pandemicflu.gov)) for peer-reviewed manuscripts and published governmental plans relevant to pandemic planning during 1978–2008. We also consulted authors’ personal files and the Internet for records of speeches, national and international conference proceedings, and other unpublished original source documents. In addition to published survey data concerning local and state response planning ([10,11](#)), we sought unpublished data from the Association of State and Territorial Health Officials, the National Association of County and City Health Officials (NACCHO), and the Council of State and Territorial Epidemiologists (CSTE).

Chronology of US Pandemic Planning

Go to: ☒

A historical overview of key milestones in US pandemic planning is provided in the [Table](#). In 1977, a federal interagency working group on influenza was formed at the request of the deputy assistant secretary for health in the Department of Health, Education, and Welfare, partly in recognition of the need for greater cooperation across government “silos.” The interagency group included representatives from the Center for Disease Control (CDC; renamed Centers for Disease Control and Prevention in 1992), the National Institutes of Health, the Food and Drug Administration (FDA), and the Department of Defense. Under CDC leadership, the work group drafted the first US pandemic plan, which was released in 1978 and included recommendations for annual influenza immunization of persons at high risk, strengthening of surveillance, expanding research, and establishing a planning and policy mechanism ([12](#)).

Table

**Timeline of selected key events in pandemic planning, United States, 1978–2008**

| Year | Event                                                                                         | Outcome or follow-up                                                                                                                |
|------|-----------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| 1978 | First US pandemic plan, drafted by Federal Interagency Working Group on Influenza             | Planning workgroup and its process assisted in strategy for addressing 1977–78 influenza A(H1N1) outbreak.                          |
| 1983 | Revision of 1978 US pandemic plan                                                             | The revised plan laid groundwork for subsequent planning documents.                                                                 |
| 1988 | Institute of Medicine report, The Future of Public Health*                                    | The report recognized the need to improve public health surveillance and response.                                                  |
| 1992 | Options for the Control of Influenza II meeting, Courchevel, France                           | The meeting led to formation of the US Federal interagency Group on Influenza Pandemic Preparedness and Emergency Response in 1993. |
| 1997 | Publication of elements of the US pandemic preparedness plan in Journal of Infectious Disease | The report updated the action plan, and a further update was published in 2002 in Clinical Infectious Diseases.                     |
| 1998 | CDC emerging infectious disease strategic plan update†                                        | Pandemic influenza was noted as an emerging infection.                                                                              |

Influenza pandemic preparedness plan for the United States. [J Infect Dis. 1997]

Influenza pandemic preparedness action plan for the United States: 2002 update. [Clin Infect Dis. 2002]

Emerg Infect Dis  
Emerg Infect Dis  
Emerg Infect Dis  
Emerg Infect Dis

|      |                                                                         |                                                                                                                   |
|------|-------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|
| 1999 | Council of State and Territorial Epidemiologists survey data published  | Enhanced influenza surveillance was recognized as a cornerstone of pandemic preparedness.                         |
| 1999 | World Health Organization Guidelines for Regional and National Planning | The World Health Organization strongly recommended all countries establish National Pandemic Planning Committees. |
| 2001 | Anthrax-related bioterrorism in the United States                       | The federal response increased state/local preparedness funding.                                                  |

[Open in a separate window](#)

\*<http://iom.edu/Reports/1988/The-Future-of-Public-Health.aspx>  
†[www.cdc.gov/mmwr/PDF/rr/rr4715.pdf](http://www.cdc.gov/mmwr/PDF/rr/rr4715.pdf)  
‡[www.flu.gov/images/reports/pi\\_vaccine\\_allocation\\_guidance.pdf](http://www.flu.gov/images/reports/pi_vaccine_allocation_guidance.pdf)

The plan was revised in 1983 to include a new recommendation to develop means to distribute and use influenza antiviral drugs (R.A. Strikas, pers. comm.). Even before completion of the pandemic plan, participants of a 1977 conference on influenza, held by the secretary of the Department of Health, Education, and Welfare, recommended continued federal support for influenza vaccination, particularly to increase vaccination levels of persons at high risk, to improve pandemic preparedness. In addition, CDC implemented a federally funded seasonal influenza immunization program, which purchased 3.4 and 2.4 million vaccine doses for the 1978–79 and 1979–80 influenza seasons, respectively, of which ≈1 million and >1.4 million doses, respectively, were administered. Initial plans were to purchase 8–9 million doses of vaccine. However, budget constraints limited vaccine purchases and ended the program after 1980 (13,14).

The next major event leading to further US pandemic planning was 1986 legislation creating the National Vaccine Program Office (NVPO), which was given a mandate to coordinate federal vaccine-related activities. At the Options for the Control of Influenza II meeting held in 1992, a consensus report identified the core components of pandemic preparedness: surveillance, vaccines, antiviral drugs, nonmedical/personal hygiene measures, communications, and enhanced annual seasonal influenza vaccination programs (15). In 1993, NVPO formed the federal interagency Group on Influenza Pandemic Preparedness and Emergency Response (GrIPPE). The group, which included nonfederal consultants and representatives from CDC, FDA, the National Institutes of Health, and the Department of Defense, drafted a pandemic planning framework that was published in 1997 (16) and updated by federal staff in 2002 (17). The GrIPPE-initiated planning documents emphasized the need for enhancements to influenza surveillance, vaccine production and distribution, antiviral drugs, influenza research, and emergency preparedness. Perhaps the most consequential outcome of GrIPPE was the creation of a core group of public health experts dedicated to pandemic planning.

Global events helped accelerate interest in pandemic planning. In 1997, Hong Kong recorded the first outbreak of avian influenza A(H5N1) virus infections in humans. Virus was transmitted from infected chickens directly to humans, and 6 of 18 persons with confirmed infection died. In late 1997, >1.5 million

Outbreak of avian influenza A(H5N1) virus infection in Hong Kong in 1997. [Clin Infect Dis. 2002]

Preparing for pandemic influenza: the need for enhanced surveillance. [Emerg Infect Dis. 1999]

Outbreak of avian influenza A(H5N1) virus infection in Hong Kong in 1997. [Clin Infect Dis. 2002]

Review Influenza pandemic preparedness. [Emerg Infect Dis. 2003]



chickens were culled throughout Hong Kong as part of successful efforts to stem the outbreak ([18](#)). This event, combined with the 2003 reemergence of A(H5N1) virus, led to concerns that the next pandemic would be caused by spread of A(H5N1) virus through Asia into Africa and Europe.

In the United States, despite the crucial role of state and local authorities in implementing pandemic plans, a 1995 CSTE survey indicated that <60% of state health departments perceived the need for a state-specific plan ([10](#)). Through a cooperative agreement between CDC and CSTE, a state and local planning effort was begun in the fall of 1995. The state Project Steering Committee included the GRIPE co-chairs and representatives from CDC, NVPO, CSTE, and the Association of Public Health Laboratories.

A meeting of >40 state and local health officials convened in September 1996 in Atlanta and identified 4 “pillars” deemed most critical for state and local pandemic preparedness efforts: 1) surveillance, 2) vaccine delivery, 3) communication and coordination, and 4) emergency response. From this meeting and subsequent subgroup meetings dedicated to the 4 pillar areas, critical elements of draft state and local guidelines were developed by January 1997. Four states (Connecticut, Missouri, New Mexico, and New York) and 1 local area (East Windsor Township, New Jersey) were selected by the state Project Steering Committee—primarily on the basis of the identification of a key project leader within each jurisdiction—and funded to pilot test the draft guidelines; 1 additional state, Maine, volunteered to test the draft guidelines without CSTE support. These 5 states conducted pilot tests during February and March 1998 and submitted results to CSTE. Findings were discussed on April 7–8, 1998, at a meeting in Atlanta. The major outcomes from pilot testing were the following recommendations: 1) a fifth pillar area, guidance for use of antiviral drugs, should be added to the guide; 2) the format of the guidelines should be more in concert with the national plan ([18](#)); and 3) all states should receive the revised guidelines to enable development of state-specific plans (R.A. Strikas, pers. comm.). These 3 issues were discussed at the Association of State and Territorial Health Officials/NACCHO annual meeting in September 1998 and incorporated into the state and local pandemic influenza planning guidelines (R.A. Strikas, pers. comm.), which were then further revised. California, Maryland, Minnesota, and South Carolina were funded through CSTE to develop state plans and submitted their model plans in April 2000.

A national pandemic influenza steering committee was subsequently formed; it was comprised of immunization program managers, emergency preparedness personnel, and representatives from CDC, CSTE, NACCHO, and the Association of Public Health Laboratories ([19](#)). A national steering committee was a logical extension as the planning process moved from a federal to a national effort.

In 2000, federal funding increased the number of states engaged in pandemic plan development. Florida, Indiana, Massachusetts, New Hampshire, and New Jersey were funded to complete plans by March 2001. In January 2001, Kansas, Washington, Nebraska, Connecticut, and New York were funded to develop plans by March 2002 ([11](#)). Throughout this process, all states received the same nominal level of funding support, which was typically used to convene a statewide stakeholders meeting. Elements critical to the planning process included technical support provided by the national steering committee and the identification of a key public health professional within each state who assumed responsibility for leading and coordinating planning efforts. Arkansas, Arizona, and Oregon concurrently developed plans of their own accord; West

**Review** Planning for the next pandemic of influenza.

[Rev Med Virol. 2001]

Virginia, Tennessee (1999), and Pennsylvania (1999) had already developed plans. Ultimately, funds were sought for every state to develop a plan.

At this early stage in the planning process, the importance of disseminating information to the broader public health community was recognized. On February 25, 1999, and July 13, 2000, CDC presented satellite videoconferences on influenza pandemic preparedness for states and local areas, which were viewed by >7,000 and ≈6,000 participants, respectively. State and local public health staff engaged in development of pandemic plans participated in the broadcasts. At a meeting of state and local planners sponsored by CSTE and CDC in Atlanta on September 12–13, 2000, detailed discussions were held regarding 1) a scenario of how an influenza pandemic might affect states in 2001; 2) how states should enhance surveillance; 3) how vaccination priorities should be determined, and 4) other national and federal pandemic planning issues, such as infection control, patient triage, and antiviral drug usage (R.A. Strikas, pers. comm.).

After the September 11, 2001, terrorist attacks on the United States, public health preparedness emerged as a priority of the federal government. In 2001, bioterrorism emergency funding support was provided to all states to assist in the nation's response to the anthrax attacks. The 2003 reemergence of avian influenza A(H5N1) infections in humans fundamentally altered the scale of pandemic preparedness. As the A(H5N1) virus spread to more countries in East and Southeast Asia during 2004–2005, concern grew among senior policymakers and public health experts that the world was on the verge of an influenza pandemic. A(H5N1) infection in humans primarily resulted from exposure to ill poultry and had a case–fatality rate of ≈60%. Substantial federal funding was provided for federal-level planning, procurement of countermeasures (e.g., vaccines and antiviral drugs), development of countermeasures, and state and local pandemic preparedness efforts (20). State health departments eventually received \$550 million to prepare for an influenza pandemic. Additional high-level policy engagement by the US federal government included the National Strategy for Pandemic Influenza, which was announced in November 2005 (21), and the White House's National Implementation Plan, which was published in May 2006 and addressed federal planning and response strategies: international transport and border control; protection of human and animal health; and security and continuity of operations issues (22).

In 2006, the Biomedical Advanced Research and Development Authority (BARDA) was established within the Department of Health and Human Services in response to the growing need for a centralized effort to coordinate research, development, and procurement of countermeasures against potential natural or intentional public health emergencies (23). BARDA preparations for a possible A(H5N1) pandemic included development of a stockpile of influenza vaccines produced by using strains circulating in poultry and wild birds in Asia (24). In addition, the US government began to purchase influenza antiviral medications for the Strategic National Stockpile sufficient to treat 25% of the US population. Additional investments were initiated to procure ventilators and personal protective equipment, such as respirators.

The US government also initiated an advanced development agenda for vaccines, therapeutics, and diagnostics. BARDA co-invested with industry to modernize vaccine production methods, with the 5-year aim of creating the capacity to produce sufficient vaccine to protect the entire US population within 6 months of the onset of an influenza pandemic (22). The US government invested in modernizing diagnostic technologies for public health

Preparing for pandemic influenza: the need for enhanced surveillance. [Emerg Infect Dis. 1999]

Update: Influenza A (H3N2)v transmission and guidelines - five states, 2011. [MMWR Morb Mortal Wkly Rep. 2012]

Surveillance for influenza during the 2009 influenza A (H1N1) pandemic-United States, April 2009-March [Clin Infect Dis. 2011]

Confronting zoonoses through closer collaboration between medicine and veterinary medicine (as 'one medic' [Vet Ital. 2007]

Use of influenza A (H1N1) 2009 monovalent vaccine: recommendations of the Advisory [MMWR Recomm Rep. 2009]

Review Influenza pandemic preparedness. [Emerg Infect Dis. 2003]

Pandemics in the age of Twitter: content analysis of Tweets during the 2009 H1N1 outbreak. [PLoS One. 2010]



laboratories. In September 2008, FDA approved specific PCR tests for a panel of influenza diagnostics to be used in CDC reference laboratories in the United States and Department of Defense laboratories around the world. This diagnostic test panel will detect and identify A(H5N1) infections and distinguish novel influenza virus infection from infection with seasonal A, B, and A(H1) and A(H3) influenza viruses. BARDA and CDC awarded contracts in November 2006 for development and evaluation of clinical point-of-care rapid diagnostics to identify seasonal influenza viruses and A(H5N1) viruses (25).

Beginning with its first published pandemic plan in 1999 (26), the World Health Organization globally promoted pandemic planning among member states, with continued planning efforts thereafter (27). The International Partnership on Avian and Pandemic Influenza was formed to coordinate support for developing countries' efforts to control the spread of A(H5N1) virus and to prepare for an influenza pandemic. This international body convened a series of meetings beginning in January 2006; these efforts generated hundreds of millions of dollars in pledges to support global pandemic preparedness and promoted a level of visibility and readiness that would not otherwise have been possible. In addition to direct financial assistance, the US government provided technical assistance to help countries develop capacities for rapid response, laboratory diagnosis, and surveillance.

The federal government recognized that the foundation for domestic pandemic response rests with state and local governments; thus, the 2005 Department of Health and Human Services strategy and the White House strategy and implementation plan called for major efforts in planning, exercising, and refining state and local preparedness. The 2006 Pandemic and All-Hazards Preparedness Act called for a review of comprehensive state pandemic preparedness plans. The federal government reviewed and scored the plans and released the results to the public in January 2009 (28); preparedness levels varied across states and across the domains that were scored. In 2008, as part of its local health profile survey, NACCHO queried local health departments about emergency preparedness and planning activities they had undertaken during the past year (29): 89% of 2,332 responding health departments said they had developed or updated pandemic influenza preparedness plans, and 86% said they had participated in tabletop drills or exercises. In addition, 76% had updated their written response plan on the basis of a postexercise after-action report, 72% had participated in a functional drill, and 49% had participated in a full-scale drill or exercise. A total of 68% of local health departments had reviewed existing state legal authorities for isolation and quarantine, and 46% had assessed the emergency preparedness competencies of staff. Only 1% of local health departments did none of the above.

## Evolution of the Pillars of Pandemic Preparedness

Go to: ☒

The 4 pandemic planning pillars—surveillance, vaccine and antiviral drug delivery, emergency response, and communication—are a solid foundation for pandemic preparation. Although state pandemic plans may have different structures, reliance on these pillars has remained more or less constant across jurisdictions and over time. The major contemporary developments in these core areas are summarized below.

Surveillance, including rapid detection of human infection with novel influenza viruses, remains a cornerstone of pandemic response. This need has been recognized since the early stage of state- and local-based planning (10). Improvements in diagnostic technology have enabled confirmation of infection

Estimating the burden of 2009 pandemic influenza A (H1N1) in the United States (April 2009–April 2010). [Clin Infect Dis. 2011]

Assessment of epidemiology capacity in State Health Departments - United States [MMWR Morb Mortal Wkly Rep. 2009]

with novel influenza viruses within hours rather than weeks. Human infection with a novel influenza virus became a nationally notifiable disease in 2007, and since then, an increased number of infections have been detected (30). Virologic surveillance is also used to determine which seasonal viruses are circulating and thus provides information for seasonal vaccine strain selection. Systems to measure the effect of seasonal influenza (i.e., pediatric deaths, hospitalizations, and syndromic surveillance) have also been enhanced. These systems have been further adapted to measure the effect of pandemic influenza (31). The need to maintain ongoing surveillance for novel influenza viruses (e.g., viruses of swine or avian origin) in humans and animals exemplifies the One Health concept (32).

In recognition that vaccine might be in short supply during the early phase of a pandemic, federal vaccine allocation guidelines were published in 2008 (33). These guidelines laid the groundwork for the pandemic vaccine priority-group recommendations put forth during the 2009 A(H1N1)pdm09 pandemic (34). Antiviral medications are critical to a pandemic response, particularly in the interval between recognition of the pandemic and the availability of vaccine. Plans for using these countermeasures have stressed the need for early treatment of affected persons and assumed that the drugs would be scarce.

It was recognized at the 1996 CSTE meeting that close coordination between emergency response staff and public health authorities is needed to develop and implement effective state and local influenza response plans. This recognition has strengthened over time. Although, states were initially not allowed to use bioterrorism funds awarded in 2001 to support pandemic planning, key emergency management concepts, including the all-hazards approach and unified incident command, were eventually integrated into planning efforts (35).

Communication, more than ever, is a fundamental component of any response effort. Timely, transparent, and proactive communication is critical, particularly in the early stages of a confirmed or suspected outbreak, when factual information is limited and the public demand for information and guidance is high. Continuous media coverage and the evolving role of social media (36) must be used to enhance communication to and from the public, particularly concerning new or evolving recommendations for disease control.

## Conclusions

[Go to:](#) ☒

Pandemic planning since 2005 had a direct and obvious effect on the response to the 2009 influenza A(H1N1)pdm09 pandemic; however, pandemic preparedness has been a feature of public health since the late 1970s. Coordinated state and federal planning processes have been a consistent feature of that planning. The pillars of pandemic planning response have remained conceptually constant: surveillance; vaccination and delivery of other medical countermeasures; emergency response coordination; and communications.

Although the 2009 A(H1N1)pdm09 pandemic spread globally within a matter of weeks, a 1918-like pandemic did not materialize. Nonetheless, this most recent pandemic resulted in ≈12,500 deaths in the United States, ≈90% of which occurred in persons <65 years of age (37). In the wake of this pandemic, the challenge in preparedness is to sustain the interest of private and public sectors in planning for a large-scale outbreak that may have a much more severe effect at a time that cannot be predicted.

Recent assessments of state level epidemiology capacity revealed potentially critical gaps in personnel and training needed for a rapid response to an

epidemic (38). There will be a need for continued commitments to support state, local, and national planning for the next infectious disease emergency. A comprehensive, coordinated, and effective response cannot be built at the time of a crisis. For future planning and response efforts, sufficient resources are required to sustain the public health response infrastructure developed during the past decade.

An effective response to a pandemic requires at least 4 distinct elements. First, material resources, such as vaccines, antiviral drugs, and personal protective equipment are essential. Second, a commitment to planning, exercising, and refining plans is necessary. Third, a sufficiently large and robustly trained workforce is the basis of any response. Fourth, a commitment to improvement is crucial. This concept extends from continuously improving plans and training to ensuring that scientific advances are incorporated into procurement and planning. One of the main lessons from the history of influenza is to expect the unexpected. Plans and training should be flexible and designed to respond to various levels of disease severity or newly identified pathogens. Benefits from pandemic preparedness will enhance our collective public health response to the next infectious disease crisis.

Go to: 

## Biography

- Dr Iskander is a senior medical consultant in the Office of the Associate Director for Science, CDC.

Go to: 

## Footnotes

*Suggested citation for this article:* Iskander J, Strikas RA, Gensheimer KF, Cox NJ, Redd SC. Pandemic influenza planning, United States, 1978–2008. *Emerg Infect Dis* [Internet]. 2013 Jun [date cited]. <http://dx.doi.org/10.3201/eid1906.121478>

<sup>1</sup>Current affiliation: US Food and Drug Administration, Office of Foods and Veterinary Medicine, College Park, Maryland, USA.

Go to: 

## References

1. World Health Organization. Pandemic influenza preparedness and response: a WHO guidance document [cited 2011 Mar 30]. [http://www.who.int/influenza/resources/documents/pandemic\\_guidance\\_04\\_2009/en/](http://www.who.int/influenza/resources/documents/pandemic_guidance_04_2009/en/)
2. US Department of Health and Human Services. About pandemics [cited 2011 Mar 30]. <http://www.pandemicflu.gov/individualfamily/about/pandemic/index.html>
3. Simonsen L, Clarke MJ, Schonberger LB, Arden NH, Cox NJ, Fukuda K. Pandemic versus epidemic influenza mortality: a pattern of changing age distribution. *J Infect Dis*. 1998;178:53–60. 10.1086/515616 [[PubMed](#)] [[CrossRef](#)] [[Google Scholar](#)]
4. Burney LE. Influenza pandemic: preparedness plans of the Public Health Service. Speech presented at International Conference on Asian Influenza; 1960. Feb 19; Bethesda, Maryland, USA [cited 2013 Apr 10]. <http://stacks.cdc.gov/>
5. Gaydos JC, Top FH Jr, Hodder RA, Russell PK. Swine influenza A outbreak, Fort Dix, New Jersey, 1976. *Emerg Infect Dis*. 2006;12:23–8. 10.3201/eid1201.050965 [[PMC free article](#)] [[PubMed](#)] [[CrossRef](#)]

[\[Google Scholar\]](#)

6. Seal JR, Spencer DJ, Meyer HM. From the National Institute of Allergy and Infectious Diseases of the National Institutes of Health, the Center for Disease Control, and the Bureau of Biologics of the Food and Drug Administration: a status report on national immunization against influenza. *J Infect Dis*. 1976;133:715–20. 10.1093/infdis/133.6.715 [\[PubMed\]](#) [\[CrossRef\]](#)

[\[Google Scholar\]](#)

7. Schonberger LB, Bregman DJ, Sullivan-Bolyai JZ. Keenlyside RA, Ziegler DW, Retalliau HF, et al. Guillain-Barré syndrome following vaccination in the National Influenza Immunization Program, United States, 1976–1977. *Am J Epidemiol*. 1979;110:105–23. [\[PubMed\]](#)

8. Fineberg HV. Preparing for avian influenza: lessons from the “swine flu affair”. *J Infect Dis*. 2008;197(Suppl 1):S14–8. 10.1086/524989 [\[PubMed\]](#)

[\[CrossRef\]](#) [\[Google Scholar\]](#)

9. Zimmer SM, Burke DS. Historical perspective—emergence of influenza A (H1N1) viruses. *N Engl J Med*. 2009;361:279–85. 10.1056/NEJMra0904322

[\[PubMed\]](#) [\[CrossRef\]](#) [\[Google Scholar\]](#)

10. Gensheimer KF, Fukuda K, Brammer L, Cox N, Patriarca PA, Strikas RA. Preparing for pandemic influenza: the need for enhanced surveillance. *Emerg Infect Dis*. 1999;5:297–9 and. 10.3201/eid0502.990219 [\[PMC free article\]](#)

[\[PubMed\]](#) [\[CrossRef\]](#) [\[Google Scholar\]](#)

11. Gensheimer KF, Meltzer MI, Postema AS, Strikas RA. Influenza pandemic preparedness. *Emerg Infect Dis*. 2003;9:1645–8. 10.3201/eid0912.030289

[\[PMC free article\]](#) [\[PubMed\]](#) [\[CrossRef\]](#) [\[Google Scholar\]](#)

12. Interagency Work Group on Pandemic Influenza. A plan for pandemic influenza. Department of Health, Education, and Welfare, 1978. [cited 2013 Apr 10]. <http://stacks.cdc.gov/>

13. Hinman AR. Influenza Immunization Program. Proceedings of the Fourteenth Immunization Conference; March 1979. [cited 2013 Apr 10].

<http://stacks.cdc.gov/>

14. Brown LK. Review and update of influenza grant programs. Proceedings of the Fifteenth Immunization Conference; 1980. Mar 10–13 [cited 2013 Apr 10].

<http://stacks.cdc.gov/>

15. Tamblyn SE, Hinman AR. Pandemic planning: conclusions and recommendations. In: Proceedings of the International Conference on Options for the Control of Influenza; Courchevel, France; 1992 Sep 27–Oct 2.

Amsterdam: Excerpta Medica; 1993. p. 457–9. [\[Google Scholar\]](#)

16. Patriarca PA, Cox NJ. Influenza pandemic preparedness plan for the United States. *J Infect Dis*. 1997;176(Suppl 1):S4–7. 10.1086/514174 [\[PubMed\]](#)

[\[CrossRef\]](#) [\[Google Scholar\]](#)

17. Strikas RA, Wallace GS, Myers MG. Influenza pandemic preparedness action plan for the United States: 2002 update. *Clin Infect Dis*. 2002;35:590–6. 10.1086/342200 [\[PubMed\]](#) [\[CrossRef\]](#) [\[Google Scholar\]](#)

18. Chan PK. Outbreak of avian influenza A(H5N1) virus infection in Hong Kong in 1997. *Clin Infect Dis*. 2002;34(Suppl 2):S58–64. 10.1086/338820

[\[PubMed\]](#) [\[CrossRef\]](#) [\[Google Scholar\]](#)

19. Gensheimer KF, Strikas RA, Fukuda K, Cox NJ, Sewell CM, Dembek ZF, et al. Influenza pandemic planning: review of a collaborative state and national

process. Int Congr Ser. 2001;1219:733–6. 10.1016/S0531-5131(01)00389-2

[CrossRef] [Google Scholar]

20. Centers for Disease Control and Prevention. Continuation guidance for cooperative agreement on public health preparedness and response for bioterrorism—budget year five, program announcement 99051, June 14, 2004. [cited 2011 Mar 29].

[http://emergency.cdc.gov/planning/continuationguidance/pdf/guidance\\_intro.pdf](http://emergency.cdc.gov/planning/continuationguidance/pdf/guidance_intro.pdf)

21. Homeland Security Council. National strategy for pandemic influenza [cited 2011 Oct 19]. 2005. <http://www.flu.gov/professional/federal/pandemic-influenza.pdf>

22. Homeland Security Council. National strategy for pandemic influenza: implementation plan [cited 2011 Mar 31]. 2006.

<http://www.pandemicflu.gov/professional/federal/pandemic-influenza-implementation.pdf>

23. US Department of Health and Human Services. BARDA Influenza and Emerging Disease Program [cited 2011 Mar 31].

<https://www.medicalcountermeasures.gov/BARDA/MCM/panflu/panflu.aspx>

24. US Food and Drug Administration. Center for Biologics Evaluation and Research. Proceedings of a meeting (2007. Feb 27) of the Vaccines and Related Biological Products Advisory Committee [cited 2013 Jan 2].

<http://www.fda.gov/ohrms/dockets/ac/07/transcripts/2007-4282t1-01.pdf>

25. US Department of Health and Human Services. Report to Congress: pandemic influenza preparedness spending [cited 2011 Mar 31].

<https://www.medicalcountermeasures.gov/BARDA/documents/hhspanflu-spending-0901.pdf>

26. Gust ID, Hampson AW, Lavanchy D. Planning for the next pandemic of influenza. Rev Med Virol. 2001;11:59–70. 10.1002/rmv.301 [PubMed]

[CrossRef] [Google Scholar]

27. World Health Organization. WHO strategic action plan for pandemic influenza 2006–2007 [cited 2012 Sep 20].

[http://www.who.int/csr/resources/publications/influenza/WHO\\_CDS\\_EPR\\_GIP\\_2006\\_2c.pdf](http://www.who.int/csr/resources/publications/influenza/WHO_CDS_EPR_GIP_2006_2c.pdf)

28. US Government Departments, Agencies, and Offices. Assessment of states' operating plans to combat pandemic influenza. Report to Homeland Security Council. 2009. [cited 2012 Sep 20].

[http://nasemso.org/documents/state\\_assessment.pdf](http://nasemso.org/documents/state_assessment.pdf)

29. National Association of County and City Health Officials. 2008 National profile of local health departments. 2009. [cited 2012 Sep 20].

[http://www.naccho.org/topics/infrastructure/profile/resources/2008report/upload/NACCHO\\_2008\\_ProfileReport\\_post-to-website-2.pdf](http://www.naccho.org/topics/infrastructure/profile/resources/2008report/upload/NACCHO_2008_ProfileReport_post-to-website-2.pdf)

30. Centers for Disease Control and Prevention. Update: influenza A (H3N2)v transmission and guidelines—five states, 2011. MMWR Morb Mortal Wkly Rep. 2012;60:1741–4. [PubMed] [Google Scholar]

31. Brammer L, Blanton L, Epperson S, Mustaquim D, Bishop A, Kniss K, et al. Surveillance for influenza during the 2009 influenza A (H1N1) pandemic—United States, April 2009–March 2010. Clin Infect Dis. 2011;52(Suppl 1):S27–35. 10.1093/cid/ciq009 [PubMed] [CrossRef] [Google Scholar]

32. Kahn LH, Kaplan B, Steele JH. Confronting zoonoses through closer

collaboration between medicine and veterinary medicine (as ‘one medicine’).

Vet Ital. 2007;43:5–19 . [\[PubMed\]](#) [\[Google Scholar\]](#)

33. US Department of Health and Human Services and US Department of Homeland Security. Guidance on allocating and targeting pandemic influenza vaccine [cited 2011 Mar 31]. 2008.

[http://www.flu.gov/images/reports/pi\\_vaccine\\_allocation\\_guidance.pdf](http://www.flu.gov/images/reports/pi_vaccine_allocation_guidance.pdf)

34. Centers for Disease Control and Prevention. Use of influenza A (H1N1) 2009 monovalent vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009. MMWR Recomm Rep. 2009;58(RR-10):1–8 . [\[PubMed\]](#) [\[Google Scholar\]](#)

35. Gensheimer KF, Meltzer MI, Postema AS, Strikas RA. Influenza pandemic preparedness. Emerg Infect Dis. 2003;9:1645–8 . 10.3201/eid0912.030289 [\[PMC free article\]](#) [\[PubMed\]](#) [\[CrossRef\]](#) [\[Google Scholar\]](#)

36. Chew C, Eysenbach G. Pandemics in the age of Twitter: content analysis of tweets during the 2009 H1N1 outbreak. PLoS ONE. 2010;5:e14118 . 10.1371/journal.pone.0014118 [\[PMC free article\]](#) [\[PubMed\]](#) [\[CrossRef\]](#) [\[Google Scholar\]](#)

37. Shrestha SS, Swardlow DL, Borse RH, Prabhu VS, Finelli L, Atkins CY, et al. Estimating the burden of 2009 pandemic influenza A (H1N1) in the United States (April 2009–April 2010). Clin Infect Dis. 2011;52(Suppl 1):S75–82 . 10.1093/cid/ciq012 [\[PubMed\]](#) [\[CrossRef\]](#) [\[Google Scholar\]](#)

38. Centers for Disease Control and Prevention. Assessment of epidemiology capacity in state health departments—United States, 2009. MMWR Morb Mortal Wkly Rep. 2009;58:1373–7 . [\[PubMed\]](#) [\[Google Scholar\]](#)

---

Articles from Emerging Infectious Diseases are provided here courtesy of **Centers for Disease Control and Prevention**

# Exhibit J



NATIONAL STRATEGY FOR  
PANDEMIC  
INFLUENZA



HOMELAND SECURITY COUNCIL

NOVEMBER 2005



NATIONAL STRATEGY FOR  
PANDEMIC  
INFLUENZA



HOMELAND SECURITY COUNCIL

NOVEMBER 2005



THE WHITE HOUSE  
WASHINGTON

My fellow Americans,

Once again, nature has presented us with a daunting challenge: the possibility of an influenza pandemic.

Most of us are accustomed to seasonal influenza, or “the flu,” a viral infection that continues to be a significant public health challenge. From time to time, changes in the influenza virus result in a new strain to which people have never been exposed. These new strains have the potential to sweep the globe, causing millions of illnesses, in what is called a pandemic.

A new strain of influenza virus has been found in birds in Asia, and has shown that it can infect humans. If this virus undergoes further change, it could very well result in the next human pandemic.

We have an opportunity to prepare ourselves, our Nation, and our world to fight this potentially devastating outbreak of infectious disease.

The *National Strategy for Pandemic Influenza* presents our approach to address the threat of pandemic influenza, whether it results from the strain currently in birds in Asia or another influenza virus. It outlines how we intend to prepare, detect, and respond to a pandemic. It also outlines the important roles to be played not only by the Federal government, but also by State and local governments, private industry, our international partners, and most importantly individual citizens, including you and your families.

While your government will do much to prepare for a pandemic, individual action and individual responsibility are necessary for the success of any measures. Not only should you take action to protect yourself and your families, you should also take action to prevent the spread of influenza if you or anyone in your family becomes ill.

Together we will confront this emerging threat and together, as Americans, we will be prepared to protect our families, our communities, this great Nation, and our world.

GEORGE W. BUSH  
THE WHITE HOUSE  
November 1, 2005

**NATIONAL STRATEGY FOR PANDEMIC INFLUENZA**

**TABLE OF CONTENTS**

**INTRODUCTION..... 1**

**THE PANDEMIC THREAT..... 1**

**THE *NATIONAL STRATEGY FOR PANDEMIC INFLUENZA* ..... 2**

**PILLARS OF THE *NATIONAL STRATEGY* ..... 3**

**IMPLEMENTATION OF THE *NATIONAL STRATEGY* ..... 3**

**PILLAR ONE: PREPAREDNESS AND COMMUNICATION..... 4**

**PILLAR TWO: SURVEILLANCE AND DETECTION ..... 7**

**PILLAR THREE: RESPONSE AND CONTAINMENT..... 8**

**ROLES AND RESPONSIBILITIES ..... 10**

## NATIONAL STRATEGY FOR PANDEMIC INFLUENZA

### INTRODUCTION

Although remarkable advances have been made in science and medicine during the past century, we are constantly reminded that we live in a universe of microbes - viruses, bacteria, protozoa and fungi that are forever changing and adapting themselves to the human host and the defenses that humans create.

Influenza viruses are notable for their resilience and adaptability. While science has been able to develop highly effective vaccines and treatments for many infectious diseases that threaten public health, acquiring these tools is an ongoing challenge with the influenza virus. Changes in the genetic makeup of the virus require us to develop new vaccines on an annual basis and forecast which strains are likely to predominate.

As a result, and despite annual vaccinations, the U.S. faces a burden of influenza that results in approximately 36,000 deaths and more than 200,000 hospitalizations each year. In addition to this human toll, influenza is annually responsible for a total cost of over \$10 billion in the U.S.

A pandemic, or worldwide outbreak of a new influenza virus, could dwarf this impact by overwhelming our health and medical capabilities, potentially resulting in hundreds of thousands of deaths, millions of hospitalizations, and hundreds of billions of dollars in direct and indirect costs. This *Strategy* will guide our preparedness and response activities to mitigate that impact.

### THE PANDEMIC THREAT

Pandemics happen when a novel influenza virus emerges that infects and can be efficiently transmitted between humans. Animals are the most likely reservoir for these emerging viruses; avian viruses played

a role in the last three influenza pandemics. Two of these pandemic-causing viruses remain in circulation and are responsible for the majority of influenza cases each year.

Pandemics have occurred intermittently over centuries. The last three pandemics, in 1918, 1957 and 1968, killed approximately 40 million, 2 million and 1 million people worldwide, respectively. Although the timing cannot be predicted, history and science suggest that we will face one or more pandemics in this century.

The current pandemic threat stems from an unprecedented outbreak of avian influenza in Asia and Europe, caused by the H5N1 strain of the Influenza A virus. To date, the virus has infected birds in 16 countries and has resulted in the deaths, through illness and culling, of approximately 200 million birds across Asia. While traditional control measures have been attempted, the virus is now endemic in Southeast Asia, present in long-range migratory birds, and unlikely to be eradicated soon.

A notable and worrisome feature of the H5N1 virus is its ability to infect a wide range of hosts, including birds and humans. As of the date of this document, the virus is known to have infected 121 people in four countries, resulting in 62 deaths over the past two years. Although the virus has not yet shown an ability to transmit efficiently between humans, as is seen with the annual influenza virus, there is concern that it will acquire this capability through genetic mutation or exchange of genetic material with a human influenza virus.

It is impossible to know whether the currently circulating H5N1 virus will cause a human pandemic. The widespread nature of H5N1 in birds and the likelihood of mutations over time raise our concerns that

the virus will become transmissible between humans, with potentially catastrophic consequences. If this does not happen with the current H5N1 strain, history suggests that a different influenza virus will emerge and result in the next pandemic.

#### **THE NATIONAL STRATEGY FOR PANDEMIC INFLUENZA**

Preparing for a pandemic requires the leveraging of all instruments of national power, and coordinated action by all segments of government and society. Influenza viruses do not respect the distinctions of race, sex, age, profession or nationality, and are not constrained by geographic boundaries. The next pandemic is likely to come in waves, each lasting months, and pass through communities of all size across the nation and world. While a pandemic will not damage power lines, banks or computer networks, it will ultimately threaten all critical infrastructure by removing essential personnel from the workplace for weeks or months.

This makes a pandemic a unique circumstance necessitating a strategy that extends well beyond health and medical boundaries, to include the sustainment of critical infrastructure, private-sector activities, the movement of goods and services across the nation and the globe, and economic and security considerations. The uncertainties associated with influenza viruses require that our *Strategy* be versatile, to ensure that we are prepared for any virus with pandemic potential, as well as the annual burden of influenza that we know we will face.

***The National Strategy for Pandemic Influenza* guides our preparedness and response to an influenza pandemic, with the intent of (1) stopping, slowing or otherwise limiting the spread of a pandemic to the United States; (2) limiting the domestic spread of a pandemic, and mitigating disease, suffering and death; and (3) sustaining infrastructure and mitigating impact to the economy and the functioning of society.**

The *Strategy* will provide a framework for future U.S. Government planning efforts that is consistent with *The National Security Strategy* and the *National Strategy for Homeland Security*. It recognizes that preparing for and responding to a pandemic cannot be viewed as a purely federal responsibility, and that the nation must have a system of plans at all levels of government and in all sectors outside of government that can be integrated to address the pandemic threat. It is guided by the following principles:

- The federal government will use all instruments of national power to address the pandemic threat.
- States and communities should have credible pandemic preparedness plans to respond to an outbreak within their jurisdictions.
- The private sector should play an integral role in preparedness before a pandemic begins, and should be part of the national response.
- Individual citizens should be prepared for an influenza pandemic, and be educated about individual responsibility to limit the spread of infection if they or their family members become ill.
- Global partnerships will be leveraged to address the pandemic threat.

---

**PILLARS OF THE *NATIONAL STRATEGY***

Our *Strategy* addresses the full spectrum of events that link a farmyard overseas to a living room in America. While the circumstances that connect these environments are very different, our strategic principles remain relevant. The pillars of our *Strategy* are:

- **Preparedness and Communication:** Activities that should be undertaken before a pandemic to ensure preparedness, and the communication of roles and responsibilities to all levels of government, segments of society and individuals.
- **Surveillance and Detection:** Domestic and international systems that provide continuous “situational awareness,” to ensure the earliest warning possible to protect the population.
- **Response and Containment:** Actions to limit the spread of the outbreak and to mitigate the health, social and economic impacts of a pandemic.

**IMPLEMENTATION OF THE *NATIONAL STRATEGY***

This *Strategy* reflects the federal government’s approach to the pandemic threat. While it provides strategic direction for the Departments and Agencies of the U.S. Government, it does not attempt to catalogue and assign all federal responsibilities. The implementation of this *Strategy* and specific responsibilities will be described separately.

## PILLAR ONE: PREPAREDNESS AND COMMUNICATION

Preparedness is the underpinning of the entire spectrum of activities, including surveillance, detection, containment and response efforts. We will support pandemic planning efforts, and clearly communicate expectations to individuals, communities and governments, whether overseas or in the United States, recognizing that all share the responsibility to limit the spread of infection in order to protect populations beyond their borders.

### *Planning for a Pandemic*

To enhance preparedness, we will:

- Develop federal implementation plans to support this *Strategy*, to include all components of the U.S. government and to address the full range of consequences of a pandemic, including human and animal health, security, transportation, economic, trade and infrastructure considerations.
- Work through multilateral health organizations such as the World Health Organization (WHO), Food and Agriculture Organization (FAO), World Organization for Animal Health (OIE) and regional organizations such as the Asia-Pacific Economic Cooperation (APEC) forum, as well as through bilateral and multilateral contacts to:
  - Support the development and exercising of avian and pandemic response plans;
  - Expand in-country medical, veterinary and scientific capacity to respond to an outbreak; and
  - Educate populations at home and abroad about high-risk practices that increase the likelihood of virus transmission between species.

- Continue to work with states and localities to:
  - Establish and exercise pandemic response plans;
  - Develop medical and veterinary surge capacity plans; and
  - Integrate non-health sectors, including the private sector and critical infrastructure entities, in these planning efforts.
- Build upon existing domestic mechanisms to rapidly recruit and deploy large numbers of health, medical and veterinary providers within or across jurisdictions to match medical requirements with capabilities.

### *Communicating Expectations and Responsibilities*

A critical element of pandemic planning is ensuring that people and entities not accustomed to responding to health crises understand the actions and priorities required to prepare for and respond to a pandemic. Those groups include political leadership at all levels of government, non-health components of government and members of the private sector. Essential planning also includes the coordination of efforts between human and animal health authorities. In order to accomplish this, we will:

- Work to ensure clear, effective and coordinated risk communication, domestically and internationally, before and during a pandemic. This includes identifying credible spokespersons at all levels of government to effectively coordinate and communicate helpful, informative messages in a timely manner.
- Provide guidance to the private sector and critical infrastructure entities on



their role in the pandemic response, and considerations necessary to maintain essential services and operations despite significant and sustained worker absenteeism.

- Provide guidance to individuals on infection control behaviors they should adopt pre-pandemic, and the specific actions they will need to take during a severe influenza season or pandemic, such as self-isolation and protection of others if they themselves contract influenza.
- Provide guidance and support to poultry, swine and related industries on their role in responding to an outbreak of avian influenza, including ensuring the protection of animal workers and initiating or strengthening public education campaigns to minimize the risks of infection from animal products.

#### ***Producing and Stockpiling Vaccines, Antivirals and Medical Material***

In combination with traditional public health measures, vaccines and antiviral drugs form the foundation of our infection control strategy. Vaccination is the most important element of this strategy, but we acknowledge that a two-pronged strategy incorporating both vaccines and antivirals is essential. To establish production capacity and stockpiles in support of our containment and response strategies, we will:

- Encourage nations to develop production capacity and stockpiles to support their response needs, to include pooling of efforts to create regional capacity.
- Encourage and subsidize the development of state-based antiviral stockpiles to support response activities.
- Ensure that our national stockpile and stockpiles based in states and communities are properly configured to respond to the diversity of medical requirements presented by a pandemic,

including personal protective equipment, antibiotics and general supplies.

- Establish domestic production capacity and stockpiles of countermeasures to ensure:
  - Sufficient vaccine to vaccinate front-line personnel and at-risk populations, including military personnel;
  - Sufficient vaccine to vaccinate the entire U.S. population within six months of the emergence of a virus with pandemic potential; and
  - Antiviral treatment for those who contract a pandemic strain of influenza.
- Facilitate appropriate coordination of efforts across the vaccine manufacturing sector.
- Address regulatory and other legal barriers to the expansion of our domestic vaccine production capacity.
- Expand the public health recommendations for domestic seasonal influenza vaccination and encourage the same practice internationally.
- Expand the domestic supply of avian influenza vaccine to control a domestic outbreak of avian influenza in bird populations.

#### ***Establishing Distribution Plans for Vaccines and Antivirals***

It is essential that we prioritize the allocation of countermeasures (vaccines and antivirals) that are in limited supply and define effective distribution modalities during a pandemic. We will:

- Develop credible countermeasure distribution mechanisms for vaccine and antiviral agents prior to and during a pandemic.



- Prioritize countermeasure allocation before an outbreak, and update this prioritization immediately after the outbreak begins based on the at-risk populations, available supplies and the characteristics of the virus.

#### ***Advancing Scientific Knowledge and Accelerating Development***

Research and development of vaccines, antivirals, adjuvants and diagnostics represents our best defense against a pandemic. To realize our goal of next-generation countermeasures against influenza, we must make significant and targeted investments in promising technologies. We will:

- Ensure that there is maximal sharing of scientific information about influenza viruses between governments, scientific entities and the private sector.
- Work with our international partners to ensure that we are all leveraging the most advanced technological approaches available for vaccine production.
- Accelerate the development of cell culture technology for influenza vaccine production and establish a domestic production base to support vaccination demands.
- Use novel investment strategies to advance the development of next-generation influenza diagnostics and countermeasures, including new antivirals, vaccines, adjuvant technologies, and countermeasures that provide protection across multiple strains and seasons of the influenza virus.

## PILLAR TWO: SURVEILLANCE AND DETECTION

Early warning of a pandemic and our ability to closely track the spread of avian influenza outbreak is critical to being able to rapidly employ resources to contain the spread of the virus. An effective surveillance and detection system will save lives by allowing us to activate our response plans before the arrival of a pandemic virus to the U.S., activate additional surveillance systems and initiate vaccine production and administration.

### *Ensuring Rapid Reporting of Outbreaks*

To support our need for “situational awareness,” both domestically and internationally, we will:

- Work through the International Partnership on Avian and Pandemic Influenza, as well as through other political and diplomatic channels such as the United Nations and the Asia-Pacific Economic Cooperation forum, to ensure transparency, scientific cooperation and rapid reporting of avian and human influenza cases.
- Support the development of the proper scientific and epidemiologic expertise in affected regions to ensure early recognition of changes in the pattern of avian or human outbreaks.
- Support the development and sustainment of sufficient U.S. and host nation laboratory capacity and diagnostic reagents in affected regions and domestically, to provide rapid confirmation of cases in animals or humans.
- Advance mechanisms for “real-time” clinical surveillance in domestic acute care settings such as emergency departments, intensive care units and laboratories to provide local, state and federal public health officials with continuous awareness of the profile of

illness in communities, and leverage all federal medical capabilities, both domestic and international, in support of this objective.

- Develop and deploy rapid diagnostics with greater sensitivity and reproducibility to allow onsite diagnosis of pandemic strains of influenza at home and abroad, in animals and humans, to facilitate early warning, outbreak control and targeting of antiviral therapy.
- Expand our domestic livestock and wildlife surveillance activities to ensure early warning of the spread of an outbreak to our shores.

### *Using Surveillance to Limit Spread*

Although influenza does not respect geographic or political borders, entry to and egress from affected areas represent opportunities to control or at the very least slow the spread of infection. In parallel to our containment measures, we will:

- Develop mechanisms to rapidly share information on travelers who may be carrying or may have been exposed to a pandemic strain of influenza, for the purposes of contact tracing and outbreak investigation.
- Develop and exercise mechanisms to provide active and passive surveillance during an outbreak, both within and beyond our borders.
- Expand and enhance mechanisms for screening and monitoring animals that may harbor viruses with pandemic potential.
- Develop screening and monitoring mechanisms and agreements to appropriately control travel and shipping of potentially infected products to and from affected regions if necessary, and to protect unaffected populations.

### PILLAR THREE: RESPONSE AND CONTAINMENT

We recognize that a virus with pandemic potential anywhere represents a risk to populations everywhere. Once health authorities have signaled sustained and efficient human-to-human spread of the virus has occurred, a cascade of response mechanisms will be initiated, from the site of the documented transmission to locations around the globe.

#### *Containing Outbreaks*

The most effective way to protect the American population is to contain an outbreak beyond the borders of the U.S. While we work to prevent a pandemic from reaching our shores, we recognize that slowing or limiting the spread of the outbreak is a more realistic outcome and can save many lives. In support of our containment strategy, we will:

- Work through the International Partnership to develop a coalition of strong partners to coordinate actions to limit the spread of a virus with pandemic potential beyond the location where it is first recognized in order to protect U.S. interests abroad.
- Where appropriate, offer and coordinate assistance from the United States and other members of the International Partnership.
- Encourage all levels of government, domestically and globally, to take appropriate and lawful action to contain an outbreak within the borders of their community, province, state or nation.
- Where appropriate, use governmental authorities to limit non-essential movement of people, goods and services into and out of areas where an outbreak occurs.
- Provide guidance to all levels of government on the range of options for

infection-control and containment, including those circumstances where social distancing measures, limitations on gatherings, or quarantine authority may be an appropriate public health intervention.

- Emphasize the roles and responsibilities of the individual in preventing the spread of an outbreak, and the risk to others if infection-control practices are not followed.
- Provide guidance for states, localities and industry on best practices to prevent the spread of avian influenza in commercial, domestic and wild birds, and other animals.

#### *Leveraging National Medical and Public Health Surge Capacity*

Rather than generating a focal point of casualties, the medical burden of a pandemic is likely to be distributed in communities across the nation for an extended period of time. In order to save lives and limit suffering, we will:

- Implement state and local public health and medical surge plans, and leverage all federal medical facilities, personnel and response capabilities to support the national surge requirement.
- Activate plans to distribute medical countermeasures, including non-medical equipment and other material, from the Strategic National Stockpile and other distribution centers to federal, state and local authorities.
- Address barriers to the flow of public health, medical and veterinary personnel across state and local jurisdictions to meet local shortfalls in public health, medical and veterinary capacity.
- Determine the spectrum of public health, medical and veterinary surge

capacity activities that the U.S. military and other government entities may be able to support during a pandemic, contingent upon primary mission requirements, and develop mechanisms to activate them.

### ***Sustaining Infrastructure, Essential Services and the Economy***

Movement of essential personnel, goods and services, and maintenance of critical infrastructure are necessary during an event that spans months in any given community. The private sector and critical infrastructure entities must respond in a manner that allows them to maintain the essential elements of their operations for a prolonged period of time, in order to prevent severe disruption of life in our communities. To ensure this, we will:

- Encourage the development of coordination mechanisms across American industries to support the above activities during a pandemic.
- Provide guidance to activate contingency plans to ensure that personnel are protected, that the delivery of essential goods and services is maintained, and that sectors remain

functional despite significant and sustained worker absenteeism.

- Determine the spectrum of infrastructure-sustainment activities that the U.S. military and other government entities may be able to support during a pandemic, contingent upon primary mission requirements, and develop mechanisms to activate them.

### ***Ensuring Effective Risk Communication***

Effective risk communication is essential to inform the public and mitigate panic. We will:

- Ensure that timely, clear, coordinated messages are delivered to the American public from trained spokespersons at all levels of government and assist the governments of affected nations to do the same.
- Work with state and local governments to develop guidelines to assure the public of the safety of the food supply and mitigate the risk of exposure from wildlife.

## ROLES AND RESPONSIBILITIES

Because of its unique nature, responsibility for preparedness and response to a pandemic extends across all levels of government and all segments of society. No single entity alone can prevent or mitigate the impact of a pandemic.

### *The Federal Government*

While the Federal government plays a critical role in elements of preparedness and response to a pandemic, the success of these measures is predicated on actions taken at the individual level and in states and communities. Federal responsibilities include the following:

- Advancing international preparedness, surveillance, response and containment activities.
- Supporting the establishment of countermeasure stockpiles and production capacity by:
  - Facilitating the development of sufficient domestic production capacity for vaccines, antivirals, diagnostics and personal protective equipment to support domestic needs, and encouraging the development of production capacity around the world;
  - Advancing the science necessary to produce effective vaccines, therapeutics and diagnostics; and
  - Stockpiling and coordinating the distribution of necessary countermeasures, in concert with states and other entities.
- Ensuring that federal departments and agencies, including federal health care systems, have developed and exercised preparedness and response plans that take into account the potential impact of

a pandemic on the federal workforce, and are configured to support state, local and private sector efforts as appropriate.

- Facilitating state and local planning through funding and guidance.
- Providing guidance to the private sector and public on preparedness and response planning, in conjunction with states and communities.

Lead departments have been identified for the medical response (Department of Health and Human Services), veterinary response (Department of Agriculture), international activities (Department of State) and the overall domestic incident management and Federal coordination (Department of Homeland Security). Each department is responsible for coordination of all efforts within its authorized mission, and departments are responsible for developing plans to implement this *Strategy*.

### *States and Localities*

Our communities are on the front lines of a pandemic and will face many challenges in maintaining continuity of society in the face of widespread illness and increased demand on most essential government services. State and local responsibilities include the following:

- Ensuring that all reasonable measures are taken to limit the spread of an outbreak within and beyond the community's borders.
- Establishing comprehensive and credible preparedness and response plans that are exercised on a regular basis.
- Integrating non-health entities in the planning for a pandemic, including law enforcement, utilities, city services and political leadership.

- Establishing state and community-based stockpiles and distribution systems to support a comprehensive pandemic response.
- Identifying key spokespersons for the community, ensuring that they are educated in risk communication, and have coordinated crisis communications plans.
- Providing public education campaigns on pandemic influenza and public and private interventions.
- Where possible, establishing mechanisms to allow workers to provide services from home if public health officials advise against non-essential travel outside the home.
- Establishing partnerships with other members of the sector to provide mutual support and maintenance of essential services during a pandemic.

### ***The Private Sector and Critical Infrastructure Entities***

The private sector represents an essential pillar of our society because of the essential goods and services that it provides. Moreover, it touches the majority of our population on a daily basis, through an employer-employee or vendor-customer relationship. For these reasons, it is essential that the U.S. private sector be engaged in all preparedness and response activities for a pandemic.

Critical infrastructure entities also must be engaged in planning for a pandemic because of our society's dependence upon their services. Both the private sector and critical infrastructure entities represent essential underpinnings for the functioning of American society. Responsibilities of the U.S. private sector and critical infrastructure entities include the following:

- Establishing an ethic of infection control in the workplace that is reinforced during the annual influenza season, to include, if possible, options for working offsite while ill, systems to reduce infection transmission, and worker education.
- Establishing contingency systems to maintain delivery of essential goods and services during times of significant and sustained worker absenteeism.
- Taking precautions to prevent the spread of infection to others if an individual or a family member has symptoms of influenza.
- Being prepared to follow public health guidance that may include limitation of attendance at public gatherings and non-essential travel for several days or weeks.
- Keeping supplies of materials at home, as recommended by authorities, to support essential needs of the household for several days if necessary.

### ***Individuals and Families***

The critical role of individuals and families in controlling a pandemic cannot be overstated. Modeling of the transmission of influenza vividly illustrates the impact of one individual's behavior on the spread of disease, by showing that an infection carried by one person can be transmitted to tens or hundreds of others. For this reason, individual action is perhaps the most important element of pandemic preparedness and response.

Education on pandemic preparedness for the population should begin before a pandemic, should be provided by all levels of government and the private sector, and should occur in the context of preventing the transmission of any infection, such as the annual influenza or the common cold. Responsibilities of the individual and families include:



### ***International Partners***

We rely upon our international partnerships, with the United Nations, international organizations and private non-profit organizations, to amplify our efforts, and will engage them on a multilateral and bilateral basis. Our international effort to contain and mitigate the effects of an outbreak of pandemic influenza is a central component of our overall strategy. In many ways, the character and quality of the U.S. response and that of our international partners may play a determining role in the severity of a pandemic.

The International Partnership on Avian and Pandemic Influenza stands in support of multinational organizations. Members of the Partnership have agreed that the following 10 principles will guide their efforts:

1. International cooperation to protect the lives and health of our people;
2. Timely and sustained high-level global political leadership to combat avian and pandemic influenza;
3. Transparency in reporting of influenza cases in humans and in animals caused by virus strains that have pandemic potential, to increase understanding and preparedness and especially to ensure rapid and timely response to potential outbreaks;
4. Immediate sharing of epidemiological data and samples with the World Health Organization (WHO) and the international community to detect and characterize the nature and evolution of any outbreaks as quickly as possible, by utilizing, where appropriate, existing networks and mechanisms;
5. Rapid reaction to address the first signs of accelerated transmission of H5N1 and other highly pathogenic influenza strains so that appropriate international and national resources can be brought to bear;
6. Prevent and contain an incipient epidemic through capacity building and in-country collaboration with international partners;
7. Work in a manner complementary to and supportive of expanded cooperation with and appropriate support of key multilateral organizations (including the WHO, Food and Agriculture Organization and World Organization for Animal Health);
8. Timely coordination of bilateral and multilateral resource allocations; dedication of domestic resources (human and financial); improvements in public awareness; and development of economic and trade contingency plans;
9. Increased coordination and harmonization of preparedness, prevention, response and containment activities among nations, complementing domestic and regional preparedness initiatives, and encouraging where appropriate the development of strategic regional initiatives; and
10. Actions based on the best available science.

Through the Partnership and other bilateral and multilateral initiatives, we will promote these principles and support the development of an international capacity to prepare, detect and respond to an influenza pandemic.





# Exhibit K

NATIONAL STRATEGY FOR  
PANDEMIC  
INFLUENZA

IMPLEMENTATION PLAN



HOMELAND SECURITY COUNCIL

MAY 2006

NATIONAL STRATEGY FOR  
PANDEMIC  
INFLUENZA  
  
IMPLEMENTATION PLAN



HOMELAND SECURITY COUNCIL

MAY 2006



THE WHITE HOUSE  
WASHINGTON

My fellow Americans,

On November 1, 2005, I announced the *National Strategy for Pandemic Influenza*, a comprehensive approach to addressing the threat of pandemic influenza. Our *Strategy* outlines how we are preparing for, and how we will detect and respond to, a potential pandemic.

Since then, our Nation has taken a series of historic steps to address the pandemic threat. In December, the Congress appropriated \$3.8 billion. The International Partnership for Avian and Pandemic Influenza, which we launched at the United Nations in September 2005, has encouraged openness and coordinated action by the international community. Here at home, we have made major investments in vaccine and antiviral development, research into the influenza virus, surveillance for disease in animals and humans, and the local, State, and Federal infrastructure necessary to respond to a pandemic. By making these critical investments, the Federal Government has begun strengthening our ability to safeguard the American people in the event of a devastating global pandemic and helping to prepare the Nation's public health and medical infrastructure.

Building upon these efforts, the *Implementation Plan for the National Strategy for Pandemic Influenza* ensures that our efforts and resources will be brought to bear in a coordinated manner against this threat. The *Plan* describes more than 300 critical actions, many of which have already been initiated, to address the threat of pandemic influenza.

Our efforts require the participation of, and coordination by, all levels of government and segments of society. State and local governments must be prepared, and my Administration will work with them to provide the necessary guidance in order to best protect their citizens. No less important will be the actions of individual citizens, whose participation is necessary to the success of these efforts.

Our Nation will face this global threat united in purpose and united in action in order to best protect our families, our communities, our Nation, and our world from the threat of pandemic influenza.

A large, stylized handwritten signature of George W. Bush in black ink.

GEORGE W. BUSH  
THE WHITE HOUSE  
May 2006

# TABLE OF CONTENTS

|                                                                                            |     |
|--------------------------------------------------------------------------------------------|-----|
| <b>PREFACE</b> .....                                                                       | vii |
| <b>CHAPTER 1 - EXECUTIVE SUMMARY</b> .....                                                 | 1   |
| THE PANDEMIC THREAT .....                                                                  | 1   |
| CHAPTER 2 - U.S. GOVERNMENT PLANNING FOR A PANDEMIC .....                                  | 1   |
| CHAPTER 3 - FEDERAL GOVERNMENT RESPONSE TO A PANDEMIC .....                                | 2   |
| CHAPTER 4 - INTERNATIONAL EFFORTS .....                                                    | 4   |
| CHAPTER 5 - TRANSPORTATION AND BORDERS .....                                               | 6   |
| CHAPTER 6 - PROTECTING HUMAN HEALTH .....                                                  | 8   |
| CHAPTER 7 - PROTECTING ANIMAL HEALTH .....                                                 | 10  |
| CHAPTER 8 - LAW ENFORCEMENT, PUBLIC SAFETY, AND SECURITY .....                             | 12  |
| CHAPTER 9 - INSTITUTIONS: PROTECTING PERSONNEL AND ENSURING CONTINUITY OF OPERATIONS ..... | 13  |
| <b>CHAPTER 2 - U.S. GOVERNMENT PLANNING FOR A PANDEMIC</b> .....                           | 15  |
| THE PANDEMIC THREAT .....                                                                  | 15  |
| THE NATIONAL STRATEGY FOR PANDEMIC INFLUENZA .....                                         | 16  |
| IMPLEMENTATION OF THE NATIONAL STRATEGY .....                                              | 17  |
| NECESSARY ENABLERS OF PANDEMIC PREPAREDNESS .....                                          | 18  |
| ADVANCING PANDEMIC PREPAREDNESS .....                                                      | 21  |
| PLANNING ASSUMPTIONS .....                                                                 | 25  |
| <b>CHAPTER 3 - FEDERAL GOVERNMENT RESPONSE TO A PANDEMIC</b> .....                         | 27  |
| COMMAND, CONTROL, AND COORDINATION OF THE FEDERAL RESPONSE .....                           | 27  |
| ROLES AND RESPONSIBILITIES .....                                                           | 29  |
| FEDERAL GOVERNMENT ACTIONS DURING A PANDEMIC .....                                         | 30  |
| SUMMARY OF FEDERAL GOVERNMENT ACTIONS DURING A PANDEMIC .....                              | 33  |
| <b>CHAPTER 4 - INTERNATIONAL EFFORTS</b> .....                                             | 43  |
| INTRODUCTION .....                                                                         | 43  |
| KEY CONSIDERATIONS .....                                                                   | 43  |
| ROLES AND RESPONSIBILITIES .....                                                           | 50  |
| ACTIONS AND EXPECTATIONS .....                                                             | 54  |
| <b>CHAPTER 5 - TRANSPORTATION AND BORDERS</b> .....                                        | 71  |
| INTRODUCTION .....                                                                         | 71  |
| KEY CONSIDERATIONS .....                                                                   | 71  |
| ROLES AND RESPONSIBILITIES .....                                                           | 82  |
| ACTIONS AND EXPECTATIONS .....                                                             | 85  |
| <b>CHAPTER 6 - PROTECTING HUMAN HEALTH</b> .....                                           | 99  |
| INTRODUCTION .....                                                                         | 99  |
| KEY CONSIDERATIONS .....                                                                   | 100 |
| ROLES AND RESPONSIBILITIES .....                                                           | 114 |
| ACTIONS AND EXPECTATIONS .....                                                             | 116 |

---

|                                                                                                   |            |
|---------------------------------------------------------------------------------------------------|------------|
| <b>CHAPTER 7 - PROTECTING ANIMAL HEALTH .....</b>                                                 | <b>137</b> |
| INTRODUCTION .....                                                                                | 137        |
| KEY CONSIDERATIONS .....                                                                          | 138        |
| ROLES AND RESPONSIBILITIES .....                                                                  | 143        |
| ACTIONS AND EXPECTATIONS .....                                                                    | 145        |
| <b>CHAPTER 8 - LAW ENFORCEMENT, PUBLIC SAFETY, AND SECURITY .....</b>                             | <b>153</b> |
| INTRODUCTION .....                                                                                | 153        |
| KEY CONSIDERATIONS .....                                                                          | 153        |
| ROLES AND RESPONSIBILITIES .....                                                                  | 159        |
| ACTIONS AND EXPECTATIONS .....                                                                    | 161        |
| <b>CHAPTER 9 - INSTITUTIONS: PROTECTING PERSONNEL AND ENSURING CONTINUITY OF OPERATIONS .....</b> | <b>165</b> |
| INTRODUCTION .....                                                                                | 165        |
| KEY CONSIDERATIONS .....                                                                          | 166        |
| ROLES AND RESPONSIBILITIES .....                                                                  | 174        |
| ACTIONS AND EXPECTATIONS .....                                                                    | 178        |
| <b>APPENDIX A .....</b>                                                                           | <b>181</b> |
| GUIDANCE FOR FEDERAL DEPARTMENT PLANNING .....                                                    | 181        |
| GUIDANCE FOR ORGANIZATIONS AND BUSINESSES .....                                                   | 182        |
| GUIDANCE FOR SCHOOLS (K-12) .....                                                                 | 185        |
| GUIDANCE FOR COLLEGES AND UNIVERSITIES .....                                                      | 188        |
| GUIDANCE FOR FAITH-BASED AND COMMUNITY-BASED ORGANIZATIONS .....                                  | 191        |
| PLANNING GUIDANCE FOR INDIVIDUALS AND FAMILIES .....                                              | 193        |
| <b>APPENDIX B .....</b>                                                                           | <b>201</b> |
| GLOSSARY OF TERMS .....                                                                           | 201        |
| <i>Acronyms</i> .....                                                                             | 201        |
| <i>Definition of Terms</i> .....                                                                  | 205        |
| <b>APPENDIX C .....</b>                                                                           | <b>211</b> |
| AUTHORITIES AND REFERENCES .....                                                                  | 211        |
| <i>Chapter 2 - U.S. Government Planning for a Pandemic</i> .....                                  | 211        |
| <i>Chapter 3 - Federal Government Response to a Pandemic</i> .....                                | 211        |
| <i>Chapter 4 - International Efforts</i> .....                                                    | 213        |
| <i>Chapter 5 - Transportation and Borders</i> .....                                               | 215        |
| <i>Chapter 6 - Protecting Human Health</i> .....                                                  | 219        |
| <i>Chapter 7 - Protecting Animal Health</i> .....                                                 | 222        |
| <i>Chapter 8 - Law Enforcement, Public Safety, and Security</i> .....                             | 224        |
| <i>Chapter 9 - Institutions: Protecting Personnel and Ensuring Continuity of Operations</i> ..... | 227        |

## PREFACE

In the last century, three influenza pandemics have swept the globe. In 1918, the first pandemic (sometimes referred to as the “Spanish Flu”) killed over 500,000 Americans and more than 20 million people worldwide. One-third of the U.S. population was infected, and average life expectancy was reduced by 13 years. Pandemics in 1957 and 1968 killed tens of thousands of Americans and millions across the world. Scientists believe that viruses from birds played a role in each of those outbreaks.

Today, we face a new threat. A new influenza strain — influenza A (H5N1) — is spreading through bird populations across Asia, Africa, and Europe, infecting domesticated birds, including ducks and chickens, and long-range migratory birds. The first recorded appearance of H5N1 in humans occurred in Hong Kong in 1997. Since then, the virus has infected over 200 people in the Eastern Hemisphere, with a mortality rate of over 50 percent.

At this time, avian influenza is primarily an animal disease. Human infections are generally limited to individuals who come into direct contact with infected birds. If the virus develops the capacity for sustained, efficient, human-to-human transmission, however, it could spread quickly around the globe. In response to this threat, the President issued the *National Strategy for Pandemic Influenza* on November 1, 2005. The *Strategy* outlines the coordinated Federal Government effort to prepare for pandemic influenza. Of equal importance, the *Strategy* underscores the critical roles that State, local, and tribal authorities, the private sector, and communities must play to address the threat of a pandemic, and the concrete steps that individuals can and should take to protect themselves and their families.

This Implementation Plan for the *National Strategy for Pandemic Influenza* further clarifies the roles and responsibilities of governmental and non-governmental entities, including Federal, State, local, and tribal authorities and regional, national, and international stakeholders, and provides preparedness guidance for all segments of society. The Plan addresses the following topics:

- **Chapters 2 and 3 (U.S. Government Planning and Response)** describe the unique threat posed by a pandemic that would spread across the globe over a period of many months; the specific and coordinated actions to be taken by the Federal Government as well as its capabilities and limitations in responding to the sustained and distributed burden of a pandemic; and the central importance of comprehensive preparation at the State, local, and community levels to address medical and non-medical impacts with available resources.
- **Chapters 4 and 5 (International Efforts and Transportation and Borders)** outline steps we will take to work with our international partners to prevent, slow, or limit the spread of infection globally and in the United States, and describe proposed measures for effective management of our borders and the transportation sector during a pandemic.
- **Chapter 6 (Protecting Human Health)** details the critical actions that public health authorities, non-governmental organizations, the private sector, and individuals should take to protect human health and reduce the morbidity and mortality caused by a pandemic.
- **Chapter 7 (Protecting Animal Health)** highlights the actions necessary to prevent and contain outbreaks in animals with the aim of reducing human exposure and the opportunity for viral mutation that could result in efficient human-to-human transmission.

- **Chapter 8 (Law Enforcement, Public Safety, and Security)** outlines the support that State and local law enforcement and public safety agencies must provide, with appropriate Federal assistance, to public health efforts and essential public safety services, and to maintain public order.
- **Chapter 9 (Institutional Considerations)** provides guidance for the preparation of essential pandemic plans by Federal, State, local, and tribal authorities, businesses, schools, and non-governmental organizations to ensure continuity of operations and maintenance of critical infrastructure. It also provides guidance for families and individuals to ensure appropriate personal protection. To address the threat of pandemic influenza, it is essential that such plans be put in place as soon as possible.

The Implementation Plan represents a comprehensive effort by the Federal Government to identify the critical steps that must be taken immediately and over the coming months and years to address the threat of an influenza pandemic. It assigns specific responsibilities to Departments and Agencies across the Federal Government, and includes measures of progress and timelines for implementation to ensure that we meet our preparedness objectives.

This Plan will be revised over time. The pandemic threat is constantly evolving, as is our level of preparedness. The actions, priorities, timelines and measures of progress will be reviewed on a continuous basis and revised as appropriate to reflect changes in our understanding of the threat and the state of relevant response capabilities and technologies. Additional details regarding the implementation of this Plan are included at the conclusion of Chapter 1.

The active engagement and full involvement of all levels of government and all segments of society, including at the community level, are critical for an effective response. Ultimately, however, the actions of individuals will be the key to our response.



## CHAPTER 1 — EXECUTIVE SUMMARY

### The Pandemic Threat

Influenza viruses have threatened the health of animal and human populations for centuries. Their diversity and propensity for mutation have thwarted our efforts to develop both a universal vaccine and highly effective antiviral drugs. A pandemic occurs when a novel strain of influenza virus emerges that has the ability to infect and be passed between humans. Because humans have little immunity to the new virus, a worldwide epidemic, or pandemic, can ensue. Three human influenza pandemics occurred in the 20th century, each resulting in illness in approximately 30 percent of the world population and death in 0.2 percent to 2 percent of those infected. Using this historical information and current models of disease transmission, it is projected that a modern pandemic could lead to the deaths of 200,000 to 2 million people in the United States alone.

The animal population serves as a reservoir for new influenza viruses. Scientists believe that avian, or bird, viruses played a role in the last three pandemics. The current concern for a pandemic arises from an unprecedented outbreak of H5N1 influenza in birds that began in 1997 and has spread across bird populations in Asia, Europe, and Africa. The virus has shown the ability to infect multiple species, including long-range migratory birds, pigs, cats, and humans. It is impossible to predict whether the H5N1 virus will lead to a pandemic, but history suggests that if it does not, another novel influenza virus will emerge at some point in the future and threaten an unprotected human population.

The economic and societal disruption of an influenza pandemic could be significant. Absenteeism across multiple sectors related to personal illness, illness in family members, fear of contagion, or public health measures to limit contact with others could threaten the functioning of critical infrastructure, the movement of goods and services, and operation of institutions such as schools and universities. A pandemic would thus have significant implications for the economy, national security, and the basic functioning of society.

### Chapter 2 — U.S. Government Planning for a Pandemic

The President announced the *National Strategy for Pandemic Influenza (Strategy)* on November 1, 2005. The *Strategy* provides a high-level overview of the approach that the Federal Government will take to prepare for and respond to a pandemic, and articulates expectations of non-Federal entities to prepare themselves and their communities. The *Strategy* contains three pillars: (1) preparedness and communication; (2) surveillance and detection; and (3) response and containment.

Preparedness for a pandemic requires the establishment of infrastructure and capacity, a process that can take years. For this reason, significant steps must be taken now. The *Strategy* affirms that the Federal Government will use all instruments of national power to address the pandemic threat. The Federal Government will collaborate fully with international partners to attempt containment of a potential pandemic wherever sustained and efficient human-to-human transmission is documented, and will make every reasonable effort to delay the introduction of a pandemic virus to the United States. If these efforts fail, responding effectively to an uncontained pandemic domestically will require the full participation of all levels of government and all segments of society. The Implementation Plan (Plan) for the *Strategy* makes it clear that every segment of society must prepare for a pandemic and will be a part of the response. The Plan further recognizes that the Federal Government must provide clear criteria and

decision tools to inform State, local, and private sector planning and response actions, and that Federal agencies must be prepared to supplement and support State and local efforts where necessary and feasible.

The *Strategy* must be translated into tangible action that fully engages the breadth of the Federal Government. This Plan provides a common frame of reference for understanding the pandemic threat and summarizes key planning considerations for all partners. It also proposes that Federal departments and agencies take specific, coordinated steps to achieve the goals of the *Strategy* and outlines expectations of non-Federal stakeholders in the United States and abroad. Joint and integrated planning across all levels of government and the private sector is essential to ensure that available national capabilities and authorities produce detailed plans and response actions that are complementary, compatible, and coordinated.

The Federal Government has already taken a historic series of actions, domestically and internationally, to address the pandemic threat. The actions include the development of a promising human vaccine against the H5N1 avian influenza virus, the submission of a \$7.1 billion budget request over several years to support pandemic preparedness, the establishment of the International Partnership on Avian and Pandemic Influenza, and the first Cabinet-level exercise to assess the Federal Government response to a naturally occurring threat.

### **Chapter 3 — Federal Government Response to a Pandemic**

The goals of the Federal Government response to a pandemic are to: (1) stop, slow, or otherwise limit the spread of a pandemic to the United States; (2) limit the domestic spread of a pandemic, and mitigate disease, suffering and death; and (3) sustain infrastructure and mitigate impact to the economy and the functioning of society (see *Stages of Federal Government Response* between Chapters 5 and 6).

Unlike geographically and temporally bounded disasters, a pandemic will spread across the globe over the course of months or over a year, possibly in waves, and will affect communities of all sizes and compositions. In terms of its scope, the impact of a severe pandemic may be more comparable to that of war or a widespread economic crisis than a hurricane, earthquake, or act of terrorism. In addition to coordinating a comprehensive and timely national response, the Federal Government will bear primary responsibility for certain critical functions, including: (1) the support of containment efforts overseas and limitation of the arrival of a pandemic to our shores; (2) guidance related to protective measures that should be taken; (3) modifications to the law and regulations to facilitate the national pandemic response; (4) modifications to monetary policy to mitigate the economic impact of a pandemic on communities and the Nation; (5) procurement and distribution of vaccine and antiviral medications; and (6) the acceleration of research and development of vaccines and therapies during the outbreak.

The center of gravity of the pandemic response, however, will be in communities. The distributed nature of a pandemic, as well as the sheer burden of disease across the Nation over a period of months or longer, means that the Federal Government's support to any particular State, Tribal Nation, or community will be limited in comparison to the aid it mobilizes for disasters such as earthquakes or hurricanes, which strike a more confined geographic area over a shorter period of time. Local communities will have to address the medical and non-medical effects of the pandemic with available resources. This means that it is essential for communities, tribes, States, and regions to have plans in place to support the full spectrum of their needs over the course of weeks or months, and for the Federal Government to provide clear guidance on the manner in which these needs can be met.

**Command, Control, and Coordination of the Federal Response during a Pandemic**

It is important that the Federal Government have a defined mechanism for coordination of its response. The *National Response Plan* (NRP) is the primary mechanism for coordination of the Federal Government's response to Incidents of National Significance, and will guide the Federal pandemic response. It defines Federal departmental responsibilities for sector-specific responses, and provides the structure and mechanisms for effective coordination among Federal, State, local, and tribal authorities, the private sector, and non-governmental organizations (NGOs). Pursuant to the NRP and Homeland Security Presidential Directive 5 (HSPD-5), the Secretary of Homeland Security is responsible for coordination of Federal operations and resources, establishment of reporting requirements, and conduct of ongoing communications with Federal, State, local, and tribal governments, the private sector, and NGOs.

A pandemic will present unique challenges to the coordination of the Federal response. First and foremost, the types of support that the Federal Government will provide to the Nation are of a different kind and character than those it traditionally provides to communities damaged by natural disasters. Second, although it may occur in discrete waves in any one locale, the national impact of a pandemic could last for many months. Finally, a pandemic is a sustained public health and medical emergency that will have sustained and profound consequences for the operation of critical infrastructure, the mobility of people and freight, and the global economy. Health and medical considerations will affect foreign policy, international trade and travel, domestic disease containment efforts, continuity of operations within the Federal Government, and many other aspects of the Federal response.

Pursuant to the NRP, as the primary agency and coordinator for Emergency Support Function #8 (Public Health and Medical Services), the Secretary of Health and Human Services will lead Federal health and medical response efforts and will be the principal Federal spokesperson for public health issues, coordinating closely with DHS on public messaging pertaining to the pandemic. Pursuant to HSPD-5, as the principal Federal official for domestic incident management, the Secretary of Homeland Security will provide coordination for Federal operations and resources, establish reporting requirements, and conduct ongoing communications with Federal, State, local, and tribal governments, the private sector, and NGOs. In the context of response to a pandemic, the Secretary of Homeland Security will coordinate overall non-medical support and response actions, and ensure necessary support to the Secretary of Health and Human Services' coordination of public health and medical emergency response efforts.

The NRP stipulates mechanisms for coordination of the Federal response, but sustaining these mechanisms for several months to over a year will present unique challenges. Day-to-day situational monitoring will occur through the national operations center, and strategic policy development and coordination on domestic pandemic response issues will be accomplished through an interagency body composed of senior decision-makers from across the government and chaired by the White House. These and other considerations applicable to response to a pandemic will be incorporated in the NRP review process and will inform recommendations on revisions and improvements to the NRP and associated annexes.

Pursuant to the NRP, policy issues that cannot be resolved at the department level will be addressed through the Homeland Security Council/National Security Council (HSC/NSC)-led policy coordination process.

## Chapter 4 — International Efforts

Pandemic influenza is a global threat requiring an international response. Given the rapid speed of transmission and the universal susceptibility of human populations, an outbreak of pandemic influenza anywhere poses a risk to populations everywhere. Our international effort to contain and mitigate the effects of an outbreak of pandemic influenza beyond our borders is a central component of our strategy to stop, slow, or limit the spread of infection to the United States.

Substantial obstacles exist to implementing a rapid response to an incipient human pandemic in many nations. The threat of pandemic influenza may not be widely recognized or understood. Many countries do not have sufficient resources or expertise to detect and respond to outbreaks independently, and lack a robust public health and communications infrastructure, pandemic preparedness plans, and proven logistics capability. International mechanisms to support effective global surveillance and response, including coordinated provision of accurate and timely information to the public, are also inadequate.

To address the international dimension of the pandemic threat, the United States will build upon a series of recent actions. The International Partnership on Avian and Pandemic Influenza was launched by the President in September 2005 to heighten awareness of the pandemic threat among governments, to promote the development of national capacity to detect and respond to a pandemic, and to encourage transparency, scientific cooperation, and rapid reporting of outbreaks in birds and humans. We will work through the Partnership, with international health organizations and bilaterally to increase global commitment, cooperation, and capacity to address the threat of avian influenza. At the Beijing Donors Conference in January 2006, the United States committed \$334 million to international efforts to prevent and counter the spread of avian and human pandemic influenza, representing approximately one-third of all international grants pledged<sup>1</sup>

### Actions to Implement the National Strategy for Pandemic Influenza

The Federal Government will work to increase awareness of the threat by foreign governments and their citizens, and promote the development of national and international capacity to prevent, detect, and limit the spread of animal and human pandemic influenza within and beyond national borders. We will work through bilateral and multilateral channels to assist priority countries, especially those in which highly pathogenic H5N1 avian influenza is endemic or emerging, to develop and exercise plans for an effective response.

#### *Establish Surveillance Capability in Countries at Risk*

A country's ability to respond quickly to a human outbreak requires a broad surveillance network to detect cases of influenza-like illnesses in people, coupled with rapid diagnostic and response capabilities. To help address these challenges, the Federal Government and international partners will work together to assist countries at risk to build and improve infrastructure at the central, provincial, and local levels. Building this capability in countries at risk will facilitate monitoring of disease spread and rapid response to contain influenza outbreaks with pandemic potential.

---

<sup>1</sup> Does not include loans of approximately \$1 billion pledged at conference

*Expand Capacity for Animal Health Activities and Press for a Strong International Leadership Role*

We will press for a strong leadership role for international animal health organizations, particularly the World Organization for Animal Health (OIE) and the United Nations (UN) Food and Agriculture Organization (FAO), to assess the animal health/veterinary services infrastructure of affected, high-risk, and at-risk countries, in order to determine areas of need that must be addressed. We will work to assist the FAO to establish a resident rapid response capability and a network that can be drawn upon to provide technical assistance to address the immediate needs of countries with incipient or advanced outbreaks of avian influenza.

*Support a Coordinated Response by the International Community in Support of National Efforts*

A series of actions will be necessary to contain an outbreak of a virus with pandemic potential, including rapid characterization of a potential outbreak, immediate and coordinated deployment of rapid reaction teams, deployment of international stocks of antiviral medications and other materiel, and institution of public health measures to limit spread. To be most effective, these measures require international preparation and coordination. The Federal Government will work with the World Health Organization (WHO), the Partnership, and through diplomatic contacts to strengthen these international mechanisms, and we will configure our own Departments and Agencies to deploy personnel and materiel in support of an international response upon the first reports of suspected outbreaks.

We will also press for the establishment of internationally agreed-upon definitions and protocols in support of a containment strategy, including:

- A global epidemiologic standard for triggering an international containment response to a potential pandemic.
- The necessary actions that should be taken by nations in response to a suspected outbreak, including prompt reporting of the outbreak to the WHO Secretariat, and sharing of viral isolates and/or tissue samples.
- The establishment of an international rapid response capability, led by the WHO but with significant contributions of personnel and equipment by the international community, to investigate and respond to the suspected beginning of a pandemic.
- The establishment of national, regional, and international stockpiles of medical and non-medical countermeasures that are pre-positioned for rapid deployment.

*Coordinate Public Communication*

We recognize that timely, accurate, credible, and coordinated messages will be necessary during a pandemic, and that inconsistent reporting or guidance within and between nations can lead to confusion and a loss of confidence by the public. We will work with the WHO and our international partners to share information as an outbreak proceeds, and to coordinate our response actions as well as the public messaging that accompanies these actions. We will also support the development of targeted and culturally sensitive communications in local languages to help the public in affected countries and countries at risk to understand the threat of influenza with pandemic potential in animals and of human pandemic influenza, the preventive measures that should be taken, and actions necessary in the event of a pandemic.

*Assist U.S. Citizens Traveling or Living Abroad*

The Federal Government will provide U.S. citizens living and traveling abroad with timely, accurate information on avian influenza, through websites, travel information, and meetings. U.S. Embassies and Consulates will identify local medical capabilities and resources that would be available to U.S. citizens in the event of a “stay in place” response to a pandemic.

## **Chapter 5 — Transportation and Borders**

The containment of an influenza virus with pandemic potential at its origin, whether the outbreak occurs abroad or within the United States, is a critical element of pandemic response efforts. Containment is most effective when approached globally, with all countries striving to achieve common goals. While complete containment might not be successful, a series of containment efforts could slow the spread of a virus to and within the United States, thereby providing valuable time to activate the domestic response.

Our Nation’s ports of entry and transportation network are critical elements in our preparation for and response to a potential influenza pandemic. Measures at our borders may provide an opportunity to slow the spread of a pandemic to and within the United States, but are unlikely to prevent it. Moreover, the sheer volume of traffic and the difficulty of developing screening protocols to detect an influenza-like illness pose significant challenges. While we will consider all options to limit the spread of a pandemic virus, we recognize complete border closure would be difficult to enforce, present foreign affairs complications, and have significant negative social and economic consequences.

Measures to limit domestic travel may delay the spread of disease. These restrictions could include a range of options, such as reductions in non-essential travel and, as a last resort, mandatory restrictions. While delaying the spread of the epidemic may provide time for communities to prepare and possibly allow the production and administration of pre-pandemic vaccine and antiviral medications, travel restrictions, per se, are unlikely to reduce the total number of people who become ill or the impact the pandemic will have on any one community. Individual regions would still experience sharp surges in the demand for medical services and the need to meet such demand with local and regional personnel, resources, and capacity. Communities, States, the private sector, and the Federal Government will need to carefully weigh the costs and benefits of transportation measures when developing their response plans, including the effectiveness of an action in slowing the spread of a pandemic, its social and economic consequences, and its operational feasibility.

Border and transportation measures will be most effective in slowing the spread of a pandemic if they are part of a larger comprehensive strategy that incorporates other interventions, such as the adherence to infection control measures (hand hygiene and cough etiquette), social distancing, isolation, vaccination, and treatment with antiviral medications.

### **Actions to Implement the National Strategy for Pandemic Influenza**

#### *Modeling to Inform Transportation and Border Decisions*

Models are powerful tools that can be used to inform policy decisions by highlighting the impact of various interventions on the spread of disease. Models can also predict the social and economic ramifications of specific transportation and movement interventions and can inform the assessment of the operational feasibility of these interventions. We will expand our infectious disease modeling



capabilities and ensure that mechanisms are in place to share the findings of these models with State and local authorities and the private sector to inform transportation decisions. We will use these models to develop guidance for State and local authorities on interventions that are likely to limit the spread of a pandemic and on protocols for implementation.

#### *Screening Mechanisms and Travel Restrictions*

Our ability to limit the spread of a pandemic, target our public health interventions, and limit the unintended consequences of these actions will be greatly enhanced by the widespread availability of cost-effective screening tools for influenza viruses such as rapid diagnostic tests. We will expand our research and development efforts to bring such tools to market as soon as possible.

The Federal Government's plan for responding to and containing pandemic outbreaks focuses on initial source containment and the use of a layered series of actions to limit spread, including traveler screening for influenza at the point of exit from a source country, en route during air travel, and upon arrival at U.S. airports. In order to ensure that international arrivals undergo proper screening protocols and are subject to isolation and quarantine if appropriate, we are likely to limit the number of airports accepting international flights early in a pandemic. Protocols will be developed to implement these policies for air travelers.

As we have done with air travel, we will establish policies to address movement of people across our land and maritime borders and the role, if any, of domestic movement restrictions. These policies and the protocols to support them will be developed in concert with State, local, and tribal stakeholders, the private sector, and our international partners.

#### *Quarantine and Isolation of Travelers*

Current Centers for Disease Control and Prevention (CDC) recommendations for managing air passengers who may be infected with an influenza virus with pandemic potential include isolation of ill persons, quarantine of all non-ill travelers (and crew), and targeted treatment and prophylaxis with antiviral medications. The Federal Government will develop criteria and protocols for isolation and quarantine of travelers early in a pandemic, prior to significant spread of the virus in the United States.

#### *Trade and Movement of Cargo*

Excluding live animal and animal product cargo, the risk of influenza transmission by cargo is low. (Inanimate ship-borne cargo poses low risk, and routine surfaces are easily decontaminated.) With appropriate protective measures for workers in specific settings, cargo shipments could continue. The development of prevention measures/protocols that provide protection against the infection of workers in specific settings (e.g., those who handle/inspect cargo) would allow cargo traffic to and from the United States to continue, and thus mitigate the economic impact of the pandemic.

#### *Sustaining the Transportation Infrastructure*

Sustaining critical transportation services during a pandemic will be crucial to keep communities functioning and emergency supplies and resources flowing. We will make it clear to State, local, tribal, and private sector entities that planning efforts should assess systemic effects such as supply chain impact, just-in-time delivery, warehousing, and logistics, and should support the development of contingency plans to address lack of critical services and delivery of essential commodities, such as chlorine for water purification, gasoline, food, and medical supplies.

## Chapter 6 — Protecting Human Health

Protecting human health is the crux of pandemic preparedness. The components of the Strategy, the elements of this Plan, and the projected allocation of resources to preparedness, surveillance, and response activities all reflect the overarching imperative to reduce the morbidity and mortality caused by a pandemic. In order to achieve this objective, we must leverage all instruments of national power and ensure coordinated action by all segments of government and society, while maintaining the rule of law, and other basic societal functions.

The cardinal determinants of the public health response to a pandemic will be its severity, the prompt implementation of local public health interventions, and the availability and efficacy of vaccine and antiviral medications. Decisions about the prioritization and distribution of medical countermeasures; the content of risk communication campaigns; the application of community infection control and public health containment (social distancing) measures; and whether and when to make adjustments in the way care is delivered are interrelated and all fundamentally determined by the ability of the pandemic virus to cause severe morbidity and mortality and the availability and effectiveness of vaccine and antiviral medications.

While a pandemic may strain hundreds of communities simultaneously, each community will experience the pandemic as a local event. In the best of circumstances, patients and health care resources are not easily redistributed; in a pandemic, conditions would make the sharing of resources and burdens even more difficult. The Federal Government is committed to expanding national stockpiles of both vaccines and antiviral medications and will provide these medical countermeasures as well as other available resources and personnel in support of communities experiencing pandemic influenza, but communities should anticipate that in the event of multiple simultaneous outbreaks, there may be insufficient medical resources or personnel to augment local capabilities. Additionally, manufacturers and suppliers are likely to report inventory shortages and supply chains may be disrupted by the effects of a pandemic on critical personnel. State, local, and tribal entities should thus anticipate that all sources of external aid may be compromised during a pandemic.

The systematic application of disease containment measures can significantly reduce disease transmission rates with concomitant reductions in the intensity and velocity of any pandemics that do occur. The goals of disease containment after a pandemic is underway are to delay the spread of disease and the occurrence of outbreaks in U.S. communities, to decrease the clinical attack rate in affected communities, and to distribute the number of cases that do occur over a longer interval, so as to minimize social and economic disruption and to minimize, so far as possible, hospitalization and death. Decisions as to how and when to implement disease containment measures will be made on a community-by-community basis, with the Federal Government providing technical support and guidance to State and local officials on the efficacy of various social distancing measures, the manner in which they can be implemented, and strategies to mitigate unintended consequences.

Government and public health officials must communicate clearly and continuously with the public now and throughout a pandemic. To maintain public confidence and to enlist the support of individuals and families in disease containment efforts, public officials at all levels of government must provide unambiguous and consistent guidance on what individuals can do to protect themselves, how to care for family members at home, when and where to seek medical care, and how to protect others and minimize the risks of disease transmission. The public will respond favorably to messages that acknowledge its concerns, allay anxiety and uncertainty, and provide clear incentives for desirable behavior. The



information provided by public health officials should therefore be useful, addressing immediate needs, but it should also help private citizens recognize and understand the degree to which their collective actions will shape the course of a pandemic.

Ensuring access to, and timely payment for, covered services during a pandemic will be critical to maintaining a functional health care infrastructure. It may also be necessary to extend certain waivers or develop incident-specific initiatives or coverage to facilitate access to care. Pandemic influenza response activities may exceed the budgetary resources of responding Federal and State government agencies, requiring compensatory legislative action.

### **Actions to Implement the National Strategy for Pandemic Influenza**

#### *Achieving National Goals for Production and Stockpiling of Vaccine and Antiviral Medications*

The Federal Government has established two primary vaccine goals: (1) establishment and maintenance of stockpiles of pre-pandemic vaccine adequate to immunize 20 million persons against influenza strains that present a pandemic threat; and (2) expansion of domestic influenza vaccine manufacturing surge capacity for the production of pandemic vaccines for the entire domestic population within 6 months of a pandemic declaration. The Federal Government has also established two primary goals for stockpiling existing antiviral medications: (1) establishment and maintenance of stockpiles adequate to treat 75 million persons, divided between Federal and State stockpiles; and (2) establishment and maintenance of a Federal stockpile of 6 million treatment courses reserved for domestic containment efforts.

To accomplish these goals, we will expand Federal, and create State, stockpiles of influenza countermeasures, as well as expand domestic vaccine manufacturing capacity. We will make substantial new investments in the advanced development of cell-culture-based influenza vaccine candidates, with a goal of establishing the domestic surge vaccine production capacity to meet our pre-pandemic stockpile and post-pandemic vaccine production goals.

#### *Prioritizing and Distributing Limited Supplies of Vaccine and Antiviral Medications*

The Federal Government is developing guidelines to assist State, local, and tribal governments and the private sector in defining groups that should receive priority access to existing limited supplies of vaccine and antiviral medications. Priority recommendations will reflect the pandemic response goals of limiting mortality and severe morbidity; maintaining critical infrastructure and societal function; diminishing economic impacts; and maintaining national security. Priorities for vaccine and antiviral drug use will vary based on pandemic severity as well as the vaccine and drug supply.

The establishment of credible distribution plans for our countermeasures is equally important. We will work with State and tribal entities to develop and exercise influenza countermeasure distribution plans, to include the necessary logistical support of such plans, including security provisions.

#### *Deploying Limited Federal Assets and Resources to Support Local Medical Surge*

Given that local and regional surge capacity will be the foundation of a community's medical response, we will expand and enhance our guidance to State, local, and tribal entities on the most effective ways to develop and utilize surge assets. Recognizing that the availability of health and medical personnel represents the most significant barrier to the care of large numbers of patients, we will establish a joint strategy for the deployment of Federal medical providers from across the U.S. Government, and will

expand and enhance programs such as the Medical Reserve Corps and the Commissioned Corps of the Public Health Service. We will also ensure that credible plans are in place to rapidly credential, organize, and incorporate volunteer health and medical providers as part of the medical response in areas that are facing workforce shortages.

#### *Establishing Real-Time Clinical Surveillance*

In order to manage an outbreak most effectively, it is necessary to establish mechanisms for “real-time” clinical surveillance in domestic acute care settings such as emergency departments, intensive care units, and laboratories to provide local, State, and Federal public health officials with continuous awareness of the profile of illness in communities. We will support local and national efforts to establish this capability by linking hospital and acute care health information systems with local public health departments, and advancing the development of the analytical tools necessary to interpret and act upon these data streams in real time.

#### *Modeling to Inform Decision Making and Public Health Interventions*

Given the power of models to inform decision making, we will establish a single interagency hub for infectious disease modeling efforts, and ensure that this effort integrates related modeling efforts (e.g., transportation decisions, border interventions, economic impact). We will also work to ensure that this modeling can be used in real time as information about the characteristics of a pandemic virus and its impact become available. Finally, we will use this capability to inform the development of more advanced guidance for State, local, and tribal entities on social distancing measures that can be employed to limit disease spread through a community.

## **Chapter 7 — Protecting Animal Health**

Influenza viruses that cause severe disease outbreaks in animals, especially birds, are believed to be a likely source for the emergence of a human pandemic influenza virus. The avian influenza type A “H5N1” virus currently found in parts of Asia, Europe, and Africa is of particular concern due to its demonstrated ability to infect both birds and mammals, including humans. Emergence of a pandemic strain could happen outside the United States or within our borders. Once a pandemic strain emerges, infections will predominantly reflect human-to-human transmission, and birds or other animals are unlikely to be a continuing source of significant virus spread in humans.

Irrespective of whether H5N1 leads to a human pandemic, these viruses have the potential to impact the U.S. poultry industry. Some avian influenza viruses cause high mortality in chickens and are referred to as highly pathogenic avian influenza (HPAI) viruses. The economic consequences of an HPAI outbreak in the United States would depend on the size, location, type, and time necessary to eradicate the outbreak. Although such eradication efforts may help to protect human health, they can result in significant costs due to poultry production losses from bird depopulation activities and from quarantine or other movement restrictions placed on birds. But eradication of these viruses also protects the production of U.S. poultry, worth about \$29 billion in 2004.

An extensive amount of influenza surveillance is currently conducted in poultry and wild birds in the United States. Commercial poultry operations are monitored for avian influenza through the National Poultry Improvement Plan, and birds moving through the U.S. live bird marketing system are also tested for avian influenza. Wild birds are examined for avian influenza viruses through efforts involving the Federal Government, State wildlife authorities, and universities.

**Actions to Implement the National Strategy for Pandemic Influenza***Bolstering Domestic Surveillance*

Although substantial surveillance activities are already in place in the United States to detect avian influenza viruses with human pandemic potential in domestic poultry, enhancing surveillance in domestic animals and wildlife will help ensure that reporting of these events will occur as early as possible. Animal populations that are most critical for additional surveillance activities are poultry and wild birds, not only in terms of increased numbers tested but also in the geographic distribution of testing to increase the probability of detection. To fully utilize data collected as part of the national surveillance for influenza viruses with pandemic potential in animal populations, we will establish capabilities for capturing, analyzing, and sharing data.

*Expanding the National Veterinary Stockpile*

A National Veterinary Stockpile, already established, contains a variety of materiel that would be necessary for a response to an influenza outbreak, including personal protection equipment (PPE), disinfectant, diagnostic reagents, and antiviral medication (for responders). In addition, there are currently 40 million doses of avian influenza vaccine for use in poultry, should an outbreak occur. We will expand this vaccine stockpile to 110 million doses.

*Educating Bird Owners*

We will expand our multilevel outreach and education campaign called “Biosecurity for the Birds” to provide disease and biosecurity information to poultry producers, especially those with “backyard” production. The program provides guidance to bird owners and producers on preventing introduction of disease and mitigating spread of disease should it be introduced, and encourages producers to report sick birds, thereby increasing surveillance opportunities for avian influenza.

*Advancing Our Domestic Outbreak Response Plans*

Regardless of where the risk for emergence exists, the Federal Government will be prepared to respond appropriately. The Federal Government has a history of success in working with the poultry industry to eradicate HPAI viruses that have been introduced into U.S. poultry. If an influenza virus with human pandemic potential is introduced into domestic birds or other animals in the United States, despite all international efforts to prevent it, action must be directed to detecting and eradicating the virus as quickly as possible. If it is found in wild birds, we will act to prevent introduction into domestic birds or other susceptible animals.

*Enhancing Infrastructure for Animal Health Research and Development*

Enhancement of our knowledge of the ecology of influenza viruses, viral evolution, novel influenza strains that emerge in animals, and the determinants of virulence of influenza viruses in animal populations is essential. We will expand our avian influenza research programs to accelerate the development of the tools necessary to detect influenza viruses in the environment, provide immunity to avian populations, and validate disease response strategies.

## Chapter 8 — Law Enforcement, Public Safety, and Security

Due to stresses placed upon the health care system and other critical functions, civil disturbances and breakdowns in public order may occur. Likewise, emergency call centers may be overwhelmed with calls for assistance, including requests to transport influenza victims. Local law enforcement agencies may be called upon to enforce movement restrictions or quarantines, thereby diverting resources from traditional law enforcement duties. To add to these challenges, law enforcement and emergency response agencies can also expect to have their uniform and support ranks reduced significantly as a result of the pandemic. Private sector entities responsible for securing critical infrastructure will face similar challenges.

While significant progress has been made since the terrorist attacks of September 11, 2001, in establishing joint investigative protocols and linkages among the key components of public health, emergency management, and law enforcement/emergency response communities, an influenza pandemic will present new challenges, and it is important that all concerned understand their respective roles and the governing legal authorities so that they can coordinate their efforts under a complex set of Federal, State, tribal, and local laws. Joint training and exercises will help prepare for an effective response to a pandemic influenza outbreak.

State and local law enforcement will normally provide the first response pursuant to State and local law. Consistent with State law, the Governor may deploy National Guard as needed to prevent or respond to civil disturbances. When State and local resources prove incapable of an effective response, the Federal Government can assist by providing Federal law enforcement personnel, and by directing the Armed Forces to assist in law enforcement and maintain order when legal prerequisites are met. Logistical and other support assistance can also be provided.

The response to an influenza pandemic could require, if necessary and appropriate, measures such as isolation or quarantine. Isolation is a standard public health practice applied to persons who have a communicable disease. Isolation of pandemic influenza patients prevents transmission of pandemic influenza by separating ill persons from those who have not yet been exposed. Quarantine is a contact management strategy that separates individuals who have been exposed to infection but are not yet ill from others who have not been exposed to the transmissible infection; quarantine may be voluntary or mandatory. The States, which enact quarantine statutes pursuant to their police powers, are primarily responsible for quarantine within their borders. The Federal Government also has statutory authority to order a quarantine to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States or from one State or possession into any other State or possession. Influenza caused by novel or re-emergent influenza viruses that are causing, or have the potential to cause, a pandemic is on the list of specified communicable diseases for which Federal quarantine is available.

### Actions to Implement the National Strategy for Pandemic Influenza

#### *Providing Guidance to State and Local Law Enforcement Entities*

We will provide State and local law enforcement with the guidance, training, and exercises needed to prepare them to respond during a pandemic influenza outbreak, including how to assist and facilitate containment measures. Similarly, we will provide Governors with specific information concerning the processes for obtaining Federal law enforcement and military assistance.

*Supporting Local Law Enforcement Activities*

While we rely upon local and State entities to maintain civil order, it is essential that we be prepared to respond in the event of a breakdown of order that cannot be handled at the local or State level. We will ensure that Federal law enforcement agencies and the military have the necessary plans to assist States with law enforcement and related activities in the event that the need arises.

## **Chapter 9 — Institutions: Protecting Personnel and Ensuring Continuity of Operations**

Unlike many other catastrophic events, an influenza pandemic will not directly affect the physical infrastructure of an organization. While a pandemic will not damage power lines, banks, or computer networks, it has the potential ultimately to threaten all critical infrastructure by its impact on an organization's human resources by removing essential personnel from the workplace for weeks or months. Therefore, it is critical that organizations anticipate the potential impact of an influenza pandemic on personnel and, consequently, the organization's ability to continue essential functions. As part of that planning, organizations will need to ensure that reasonable measures are in place to protect the health of personnel during a pandemic.

The Federal Government recommends that government entities and the private sector plan with the assumption that up to 40 percent of their staff may be absent for periods of about 2 weeks at the height of a pandemic wave, with lower levels of staff absent for a few weeks on either side of the peak. Absenteeism will increase not only because of personal illness or incapacitation but also because employees may be caring for ill family members, under voluntary home quarantine due to an ill household member, minding children dismissed from school, following public health guidance, or simply staying at home out of safety concerns.

Public and private sector entities depend on certain critical infrastructure for their continued operations. Critical infrastructure encompasses those systems and assets that are so vital to the United States that the incapacity or destruction of such systems and assets would have a debilitating impact on security, national economic security, and national public health or safety. Critical infrastructure protection entails all the activities directed at safeguarding indispensable people, systems (especially communications), and physical infrastructure associated with the operations of those critical infrastructure sectors. Over 85 percent of critical infrastructure is owned and operated by the private sector. Therefore, sustaining the operations of critical infrastructure under conditions of pandemic influenza will depend largely on each individual organization's development and implementation of plans for business continuity under conditions of staffing shortages and to protect the health of their workforces.

Infection control measures are critically important for the protection of personnel. The primary strategies for preventing pandemic influenza are the same as those for seasonal influenza: (1) vaccination; (2) early detection and treatment; and (3) the use of infection control measures to prevent transmission. However, when a pandemic begins, a vaccine may not be widely available, and the supply of antiviral drugs may be limited. The ability to limit transmission and delay the spread of the pandemic will therefore rely primarily on the appropriate and thorough application of infection control measures in health care facilities, the workplace, the community, and for individuals at home.

Simple infection control measures may be effective in reducing the transmission of infection. There are two basic categories of intervention: (1) *transmission interventions*, such as the use of facemasks in health care settings and careful attention to cough etiquette and hand hygiene, which might reduce the

likelihood that contacts with other people lead to disease transmission; and (2) *contact interventions*, such as substituting teleconferences for face-to-face meetings, the use of other social distancing techniques, and the implementation of liberal leave policies for persons with sick family members, all of which eliminate or reduce the likelihood of contact with infected individuals. Interventions will have different costs and benefits, and be more or less appropriate or feasible, in different settings and for different individuals.

### **General Provisions**

This Plan provides initial guidance for Federal and non-Federal entities, including State, local, and tribal entities, businesses, schools and universities, communities, and NGOs, on the development of their institutional plans and provides initial guidance for individuals and families on ways that they can prepare for a pandemic. This guidance will be expanded and refined over time, in consultation with the above stakeholders.

As part of their planning, organizations will need to ensure that reasonable measures are in place to protect the health of Americans during a pandemic, sustain critical infrastructure, and mitigate impact to the economy and the functioning of society. The collective response of all Americans will be crucial in mitigating the health, social, and economic effects of a pandemic (see *Individual, Family, and Community Response to Pandemic Influenza* between Chapters 5 and 6).

The actions directed in this Plan will be implemented in a manner consistent with applicable law and subject to availability of appropriations. Nothing in this Plan alters, or impedes the ability to carry out, existing authorities or responsibilities of Federal department and agency heads to perform their responsibilities under law and consistent with applicable legal authorities and Presidential guidance.

The actions directed in this plan are intended only to improve the internal management of the executive branch of the Federal Government, and they are not intended to, and do not, create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its departments, agencies, or other entities, its officers or employees, or any other person.



## CHAPTER 2 — U.S. GOVERNMENT PLANNING FOR A PANDEMIC

### The Pandemic Threat

Influenza viruses have threatened the health of animal and human populations for centuries. Their diversity and propensity for mutation have thwarted our efforts to develop both a universal vaccine and highly effective antiviral drugs. As a result, and despite annual vaccination programs and modern medical technology, influenza in the United States results in approximately 36,000 deaths and 226,000 hospitalizations each year.

A pandemic occurs when a wholly new strain of influenza virus emerges that has the ability to infect and be passed between humans. Because humans have little immunity to the new virus, a worldwide epidemic, or pandemic, can ensue. Three human influenza pandemics occurred in the 20th century, each resulting in illness in approximately 30 percent of the world population and death in 0.2 percent to 2 percent of those infected. Using this historical information and current models of disease transmission, it is projected that a modern pandemic could lead to the deaths of 200,000 to 2 million U.S. citizens.<sup>2</sup>

The animal population serves as a reservoir for new influenza viruses. Scientists believe that avian, or bird, viruses played a role in the last three pandemics. The current concern for a pandemic arises from an unprecedented outbreak of H5N1 influenza in birds. In 1997, the H5N1 influenza virus emerged in poultry in Hong Kong and infected 18 people, 6 of whom died. Since then, the virus has spread across bird populations in Asia, Europe, and Africa resulting in the deaths, through illness and culling, of over 200 million birds. In addition, the virus has shown the ability to infect multiple species, including long-range migratory birds, pigs, cats, and humans. To date, the virus is known to have infected over 200 persons in the Eastern Hemisphere, and resulted in the deaths of more than half of those known to be infected. This mortality rate is due in part to the fact that H5 influenza viruses have not previously circulated in humans, so the population has no background immunity to these viruses. It is impossible to predict whether the H5N1 virus will lead to a pandemic, but history suggests that if it does not, another novel influenza virus will emerge at some point in the future and threaten an unprotected human population.

While a pandemic will lead to a significant toll that is measured in human illness and death, its impact will extend far beyond hospitals, infirmaries, and doctors' offices. Because influenza viruses do not respect geography, age, race, or gender, the impact of a pandemic will be pervasive, removing essential personnel from the workplace for weeks, due to their own illness, illness in a family member, or as a result of public health guidance to limit contact with others. Absenteeism across multiple sectors will threaten the functioning of critical infrastructure providers, the movement of goods and services, and operation of anchor institutions such as schools and universities. This has significant ramifications for the economy, national security, and the basic functioning of society.

The economic repercussions of a pandemic could be significant. The Congressional Budget Office has estimated that a pandemic on the scale of the 1918 outbreak could result in a loss of 5 percent of gross

<sup>2</sup> A Potential Influenza Pandemic: Possible Macroeconomic Effects and Policy Issues.  
Congressional Budget Office, December 8, 2005

domestic product, or a loss of national income of about \$600 billion. These effects will occur through two main channels. A pandemic will affect the economy directly through illness and mortality caused by the disease, and the associated lost output. A pandemic will also generate indirect costs, from actions taken to prevent and control the spread of the virus. Some of these actions will be taken by the government. Others will be taken by institutional leaders and employers, while still others will be the result of uncoordinated individual responses to avoid infection. These latter reactions will reflect public perceptions and fears.

Preparedness for a pandemic requires the establishment of infrastructure and capacity, a process that can take years. For this reason, significant steps must be taken now. This Implementation Plan (Plan) for the *National Strategy for Pandemic Influenza (Strategy)* acknowledges this reality, and makes it clear that every segment of society must prepare for a pandemic and will be a part of the response. The Plan further recognizes that the Federal Government must provide clear criteria and decision tools to inform State, local, tribal, and private sector planning and response actions, and that Federal agencies must be prepared to supplement and support State, local, and tribal efforts where necessary and feasible.

## **The National Strategy for Pandemic Influenza**

Pandemics represent a unique threat to the health and well being of human populations and ultimately to the functioning of society. As products of a complex ecosystem, their timing cannot be predicted and their emergence cannot be controlled. Because novel influenza viruses meet little immunological resistance in the population, their impact is widespread and can be severe, threatening the functioning of all elements of society. The recognition of this potential impact has led governments around the globe to accelerate their planning efforts to combat and prepare for a pandemic. It has also led governments and international health organizations around the globe to call for transparency in reporting of cases of pandemic influenza, scientific cooperation to characterize the virus and develop effective vaccines, and coordinated international plans to stop, slow, or limit the spread of a pandemic virus after it emerges.

In response to this threat, the President announced the *National Strategy for Pandemic Influenza* on November 1, 2005. The *Strategy* provides a high-level overview of the approach that the Federal Government will take to prepare for and respond to a pandemic, and articulates expectations of non-Federal entities to prepare themselves and their communities.

The *Strategy* contains three pillars: (1) preparedness and communication, (2) surveillance and detection, and (3) response and containment. Each pillar describes domestic and international efforts, animal and human health efforts, and efforts that will be undertaken at all levels of government and in communities to prepare for and respond to a pandemic. It describes the manner in which the Federal Government will support preparedness efforts domestically and internationally in regions affected by avian influenza outbreaks, including the establishment of vaccine and antiviral production capacity and stockpiles; mechanisms to ensure timely coordinated messages to the public, whether from Federal, State, local, or tribal entities, or international authorities; establishment of early warning systems that allow us to activate our response mechanisms and the production and administration of vaccine before the arrival of a pandemic to our shores; and coordinated responses domestically and internationally to limit the spread of disease and mitigate disease, suffering and death.

The *Strategy* makes it clear that the Federal Government will use all instruments of national power to address the pandemic threat. However, if efforts to contain the outbreak at its source fail, the resources of the Federal Government will not be sufficient to prevent the spread of a pandemic across the Nation and



its resulting impact on communities, workplaces, families, and individuals. An effective response will require the full participation of all levels of government and all segments of society.

## **Implementation of the *National Strategy***

While the *Strategy* provides an important framework for Federal Government planning for an influenza pandemic, it must be translated to tangible action that fully engages the breadth of the Federal enterprise. This Plan proposes that Federal departments and agencies take specific, coordinated steps to achieve the goals of the *Strategy*. Because preparedness and response activities depend upon entities outside of the Federal Government, it also outlines expectations with respect to non-Federal stakeholders in the United States and abroad. Joint and integrated planning across all levels of government and the private sector is essential to ensure that available national capabilities and authorities produce detailed plans and response actions that are complementary, compatible, and coordinated.

This Plan supports Homeland Security Presidential Directive 8 (HSPD-8) by identifying coordinated preparedness and response actions to combat pandemic influenza. All actions in this Plan emphasize jointness and coordination of effort between and among Federal, State, tribal, and local entities. The purpose of HSPD-8 is to establish “policies to strengthen the preparedness of the United States to prevent and respond to threatened or actual domestic terrorist attacks, major disasters, and other emergencies by requiring a national domestic all-hazards preparedness goal, establishing mechanisms for improved delivery of Federal preparedness assistance to State and local governments, and outlining actions to strengthen preparedness capabilities of Federal, State, and local entities.”

Because it is essential for all institutions to develop their own pandemic plans, this Plan provides guidance for non-Federal entities on the development of their institutional plans, including State, local, and tribal entities, businesses, schools and universities, and non-governmental organizations (NGOs). It also provides guidance for individuals and families on ways that they can prepare for a pandemic. Additional resources to support this planning are available at [www.pandemicflu.gov](http://www.pandemicflu.gov). Federal agencies are expected to further supplement this Plan with guidance on pandemic planning for their respective stakeholders.

Finally, this Plan describes the series of actions that the Federal Government will take when an influenza virus with pandemic potential is identified in the human population anywhere in the world, recognizing that while we are devoting significant resources to early warning and containment overseas, a pandemic strain of influenza virus could also originate in the United States.

This Plan is divided into chapters that address the breadth of major considerations raised by a pandemic: protecting human health, protecting animal health, international considerations, transportation and borders, security considerations and institutional considerations. The chapters include the following:

- Narrative descriptions of the scope of the challenges and key considerations, followed by the rationales underlying the Federal Government approach;
- The roles and responsibilities of Federal departments and agencies, State, local, and tribal entities, the private sector, and individuals and families;
- A comprehensive set of over 300 actions for Federal departments and agencies to address the pandemic threat, each accompanied by lead and supporting agencies, outcome measures, and timelines for action; and

- Clearly defined expectations for non-Federal stakeholders.

An appendix at the end of this Plan provides a brief description of relevant legal authorities in each chapter, as well as the manner in which the Federal Government will implement the Plan.

While this Plan proposes that departments and agencies to undertake a series of actions in support of the *Strategy*, it does not describe the operational details of how departments will accomplish these objectives. Departmental pandemic plans will provide those details, and will address additional considerations raised during a pandemic, including (1) protection of employees, (2) maintenance of essential functions and services, and (3) the manner in which departments and agencies will communicate messages about pandemic planning and response to their stakeholders. Specific guidance on the development of department plans is included in Chapter 9 and Appendix A.

The proposals contained within this Plan build upon a historic and comprehensive set of actions taken by the Federal Government in 2005 to address the pandemic threat. The actions include the development of a promising human vaccine against the H5N1 avian influenza virus, the submission of a \$7.1 billion budget request to support pandemic preparedness, the establishment of the International Partnership on Avian and Pandemic Influenza, and the first Cabinet-level exercise to assess the Federal Government response to a naturally occurring threat.

## **Necessary Enablers of Pandemic Preparedness**

### **View Pandemic Preparedness as a National Security Issue**

A complex balance exists between humans and the microbial world. We are forced to take notice when this balance is disrupted, but antimicrobials and medical therapies usually allow us to restore the steady state to which we have become accustomed, limiting the impact of infectious disease to an individual or a community. Because our public health and medical system is well equipped to deal with the routine challenges presented by the microbes around us, the impact of infectious diseases and the policies and procedures that guide our actions remain largely within the purview of these communities.

The pandemic threat is different. In the event of a pandemic, the transmissibility of influenza viruses, the universal susceptibility of the world's population to viruses that have not previously circulated, and the mobility of human populations mean that every corner of the globe and every element of society are likely to be touched. This has ramifications not only for the health and well being of populations, but for the national and economic security of nations, and the functioning of society. Once this fundamental premise is recognized, the scope and scale of the measures necessary to prepare for a pandemic become apparent.

### **Promote Connectivity**

One of our greatest vulnerabilities is the lack of connectivity between communities responsible for pandemic preparedness. This applies to the coordination of efforts between nations, between the health and non-health communities, between the public health and medical communities, and between the animal and human health communities.

#### *Public Health and Medical Communities*

In the United States, the public health community has responsibility for community-wide health promotion and disease prevention and mitigation efforts, and the medical community is largely focused

on action at the individual level. Insufficient communication and coordination between these communities represents a vulnerability in our preparedness for an influenza outbreak. During a pandemic, the medical community must have awareness of the ongoing epidemiological analysis and community-wide interventions being recommended by public health leaders, and the public health community must have situational awareness of the evolution of disease that can only come from connectivity to the emergency departments and other acute care settings where patients with influenza are presenting. The inter-pandemic period presents an opportunity to establish and test these relationships.

#### *International Community*

Given that viruses do not respect borders, and that one country's actions will have ramifications for the rest of the globe, we should work to align pandemic preparedness and response efforts across nations. The international community should conform to pre-specified standards for disease reporting, scientific cooperation, public health measures to limit disease spread, and the range of related measures that support our objectives of early warning and rapid response. Early adoption of the International Health Regulations by nations represents an important step in this direction, as does the commitment by nations to the principles of the International Partnership on Avian and Pandemic Influenza. The international community must build upon these agreements to establish coordinated national policies, protocols, and procedures to ensure that we have a consistent response across nations upon the emergence of a pandemic virus.

#### *Health and Non-Health Communities*

Because the impact of a pandemic will be felt across society, it is essential that all institutions prepare for what would normally be left to the purview of the health and medical communities. This requires a shift in thinking for most governmental and non-governmental entities, particularly businesses, which may not be accustomed to planning around health considerations. While these organizations have a responsibility to plan on behalf of their employees, customers, students, and other stakeholders, it is incumbent upon the health and medical communities to provide guidance on how to accomplish this planning. This can only be accomplished through the establishment of relationships between the health community and agencies across the government and entities across the community.

#### *Animal and Human Health Communities*

Animals serve as a limitless reservoir for new human pathogens. While influenza viruses have demonstrated this over centuries, we have also learned this lesson from HIV and the virus responsible for SARS. We must address the barriers between the animal and human health communities that exist at all levels of government, between NGOs, within academia, and in the community. These barriers have impeded international preparedness and response efforts to the ongoing pandemic in birds, have delayed our recognition of threats to human health, and ultimately have contributed to the overall risk of an avian virus adapting itself to the human host. While cooperation is improving between these sectors domestically, we must encourage the same between ministries of agriculture and health in other nations, and require this of the multilateral organizations that represent these communities.

### **Communicate Risk and Responsibility**

Uncertainty during a pandemic will drive many of the outcomes we fear, including panic among the public, unpredictable, and unilateral actions by governments, instability in markets, and potentially

devastating impacts on the economy. The need for timely, accurate, credible, and consistent information that is tailored to specific audiences cannot be overstated. This requires coordinated messaging by spokespersons across government, at the local, State, tribal, and Federal levels, and by our international partners. It also requires the designation and training of a cadre of spokespersons within relevant organizations, the ability to provide guidance in the setting of incomplete information, and the acknowledgement that this guidance may change as more information becomes available. Such a capability should be developed before a pandemic, as should the key messages that we know we will have to communicate upon the emergence of a pandemic virus.

As important as it will be to provide clear guidance during a pandemic, it is equally important to communicate expectations and responsibilities of all relevant stakeholders before a pandemic begins. Disease transmission occurs on an individual basis, and the outbreak of an infectious disease represents the summation of innumerable individual actions. Actions taken at the individual level do matter, as do actions by all organizations, irrespective of their size.

The need for individual and organizational participation in pandemic planning is amplified by the fact that governments and the Federal Government in particular, have limited ability to impact the spread of disease at the community level. Moreover, we can predict that the Federal Government will have limited capacity to augment the health and other infrastructure needs of specific communities when the entire Nation is overwhelmed. This reality, and the concomitant requirement for local self-sufficiency, must be communicated to States, communities, organizations, commercial enterprises, and even individuals before a pandemic begins.

### **Support Multilateral Organizations**

A pandemic is a global threat that has the potential to impact every nation. Because an outbreak in any location in the world threatens all nations, it is critically important that the international community coordinate its preparedness and response activities. Nowhere is this more apparent than in our containment planning efforts. This requires international standards for surveillance, transparency, sample sharing, and swift coordinated action upon the recognition of an outbreak. It also requires the presence of credible and independent arbiters of scientific and epidemiologic information as it becomes available.

The World Health Organization (WHO) represents the linchpin of international preparedness and response activities. It is bolstered by other multilateral and bilateral organizations, but during a pandemic we will rely upon it to be a highly visible and credible coordinator of the international response. Given the critical role that it plays, it is essential that the international community support its efforts with resources and personnel, and expand plans to provide emergency increases in capacity when the emergence of a pandemic virus is suspected or confirmed.

As we take action to support the efforts of the WHO, we must draw attention to the need to expand and enhance coordination of international animal health efforts. Given the near certainty that the next pandemic will emerge from an animal reservoir, it is critically important that the multilateral organizations responsible for animal health, particularly the United Nations (UN) Food and Agriculture Organization (FAO), be prepared to assist nations that are in the midst of or threatened by an outbreak of avian influenza.

### **Merge Preparedness for Natural and Deliberate Threats**

While the initial events leading to a deliberate or natural outbreak of infectious disease are dramatically different, the actions necessary to prepare, provide early warning, and respond are nearly identical. We

should make this principle explicit in our planning for outbreaks and ensure, to the extent possible, that the mechanisms that we put in place are mutually supportive. This has clear implications for the manner in which the Federal Government directs its biodefense resources, but it similarly places a responsibility upon the public health community to ensure that the infrastructure established at the State, local, and tribal levels to support traditional public health priorities is configured to meet our biodefense requirements.

## Advancing Pandemic Preparedness

The U.S. Government has already taken a historic series of actions, domestically and internationally, to address the pandemic threat:

- **The *National Strategy for Pandemic Influenza*** was announced on November 1, 2005, and provides strategic direction for all Federal departments and agencies, and clearly articulates expectations of non-Federal stakeholders, in pandemic preparedness, surveillance, and response. It also outlines a strategy for establishing domestic vaccine and antiviral medication production and stockpile capacity to protect the population and limit the spread of a pandemic virus in the United States and to provide treatment to those who become ill. The *Strategy* is supported by this Plan and department and agency-specific pandemic plans.
- **An Emergency Budget Request of \$7.1 billion to support activities over several years** was submitted to Congress to support the objectives of the *Strategy*. An initial appropriation in FY06 of \$3.8 billion has been made to support the budget requirements of the first year of the initiative. While much of the funding is directed toward domestic preparedness and the establishment of countermeasure stockpile and production capacity, over \$400 million is directed to bilateral and multilateral international efforts and builds upon the \$25 million appropriation of funds in the emergency Tsunami Appropriation Act Supplemental of 2005. Key programs that will be supported by the funds appropriated to date:
  - Expansion of domestic vaccine production capacity to provide greater quantities of this critical medical countermeasure than now is possible. The primary objective, depending upon availability of future appropriations and the responsiveness of the vaccine industry, is for domestic manufacturers to be able to produce enough vaccine for the entire U.S. population within 6 months of the recognition of a human influenza virus with pandemic potential. A supporting objective is to develop and maintain a standing stockpile of vaccine to protect 20 million U.S. citizens against each currently circulating influenza virus (currently avian H5N1 virus) that could become a virus with human pandemic potential.
  - Expansion of stockpiles of antiviral medications to treat more U.S. citizens than current stockpiles will allow. The primary objective, depending upon the availability of future appropriations and global production capacity, is to acquire sufficient drugs to treat 75 million U.S. citizens, or 25 percent of the U.S. population, during an influenza pandemic plus 6 million courses to be directed to containment of initial outbreaks in the United States.
  - Expansion of surveillance capabilities domestically and internationally, in humans and animals, to provide early warning of a pandemic and its arrival to our shores, and to target public health interventions during a pandemic.
  - Investments in the development of risk communication strategies, to ensure that timely, credible, and consistent messages are being provided to the public by all authorities before and during a pandemic.

- Investments in multilateral organizations and on a bilateral basis to expand scientific, public health, surveillance, and response capacity in countries currently affected by the H5N1 avian outbreak.

*Enhancing Domestic Preparedness*

- **Over \$6 billion has been invested in State and local public health and medical preparedness since 2002 for activities that directly support pandemic preparedness.** The development of pandemic plans by States has been a requirement of the Centers for Disease Control and Prevention Cooperative Agreements and the Health Resources and Services Administration Hospital Bioterrorism Preparedness Grants since 2004.
- **Real-time surveillance of disease in communities is being established by the BioSense Real-Time Clinical Connections Program,** in order to provide real-time “situational awareness” to public health officials in communities across the country during a pandemic and to facilitate the targeting of public health interventions. Ten cities were chosen to initiate the program, with a goal of including all 31 BioWatch communities by the end of 2006.
- **The Department of Homeland Security (DHS) has established a National Biosurveillance Integration System** to collect, integrate, and analyze domestic and international all-source information. The system will integrate human disease, agriculture, food, and environmental surveillance systems.
- **A Cabinet-level tabletop exercise of the Federal Government response to a pandemic** was held in December 2005 to identify and address gaps in capabilities and coordination. The exercise was the first of its kind to test the Federal response to any event, natural or deliberate, and highlighted key policy issues that are currently being addressed and resolved. The exercise will lay the foundation for ongoing assessments of Federal preparedness for a pandemic.
- **The Department of Health and Human Services’ (HHS) pandemic influenza plan** and guidance for State, local, and tribal preparedness was released on November 2, 2005. It provides comprehensive guidance for States, communities, tribal entities, hospitals, health care providers, and individuals on actions that they should take to prepare for a pandemic.
- **An HHS National meeting of States** was held in Washington, D.C., in December 2005 to provide guidance on the development of State and local pandemic preparedness and response plans. A series of more than 60 local summits on pandemic preparedness, encompassing all 50 States, will be completed in the first half of 2006.
- **The proposed Federal quarantine regulations,** which have been published for public comment, contain enhanced reporting mechanisms and procedures for conducting epidemiologic investigations, and influenza viruses with pandemic potential have been added to the list of quarantinable diseases.
- **A Memorandum of Understanding has been signed by HHS and DHS** to ensure coordination of border screening activities and information sharing for contact tracing during an outbreak of a communicable disease and references operating guidelines specific to H5N1.

*Developing, Producing, and Stockpiling Vaccines and Antiviral Medications*

- **Human vaccines against the H5N1 avian influenza virus have been developed** in conjunction with manufacturers and are undergoing testing by HHS. Vaccine will be stockpiled to provide an



immediately available supply of “pre-pandemic” H5N1 vaccine while a new vaccine tailored to the specific virus that emerges is developed after a pandemic begins.

- **Investments have been made since 2004 to advance cell culture technology for the production of influenza vaccine.**
- **Over 4 million treatment courses of antiviral medications are held in the Strategic National Stockpile (SNS),** with plans to expand to 50 million courses in the SNS, and another 31 million courses in State-based stockpiles, the procurement of which will be subsidized by the Federal Government.
- **Added procedures for comprehensive liability protection for pandemic and epidemic countermeasure manufacturers, distributors, program planners, persons who prescribe, administer, and dispense countermeasures, officials, agents, and employees of each of these entities, and a compensation program** have been put in place through legislation that was introduced and passed in 2005, thereby removing a major impediment to the establishment of a domestic vaccine production base, while ensuring that those who are harmed by a pandemic vaccine receive compensation.

#### *Enhancing International Cooperation, Capacity, and Preparedness*

- **The International Partnership on Avian and Pandemic Influenza** was launched by the United States on September 14, 2005, to ensure transparency, scientific cooperation, rapid reporting of cases, donor coordination, and a series of other actions to support global preparedness and response. The Partnership will increase cooperation among participating countries and international organizations including WHO, FAO, and the World Organization for Animal Health to develop global capacity to address an incipient pandemic. The Partnership agreed at its first meeting in Washington, D.C., in October 2005 to elevate pandemic influenza on national agendas, coordinate efforts among donor and affected nations, mobilize and leverage resources globally, and increase transparency in disease reporting and surveillance and building capacity.
- **The United States is working on a bilateral basis to support local, national, and regional efforts to build capacity, increase reporting, ensure scientific cooperation, and enhance overall preparedness.** The United States, Indonesia, and Singapore also agreed to create a model avian influenza-free zone in Indonesia to develop and demonstrate best practices to prevent infection and spread of a pandemic virus in both animals and humans. The Regional Emerging Disease Intervention Center in Singapore, jointly staffed by Singapore and the United States, is conducting training on avian influenza in Southeast Asia and developing the model for the Joint Avian Influenza Demonstration Project. The United States also is working with China to strengthen vaccine development, disease surveillance and rapid response, and pandemic planning through the U.S.-China Joint Initiative on Avian Influenza. Given the challenge of containing an outbreak of a pandemic virus on the North American continent, the United States has also begun discussions with Canada and Mexico to develop an agreed doctrine to respond to and contain a pandemic.
- **Working through existing multilateral frameworks to advance the goals of the Partnership.**
  - WHO: The United States is assisting WHO in the development of a response and containment protocol for consideration and adoption by the World Health Assembly. In addition, the United States is supporting other WHO efforts at improving the detection and response capabilities of other countries and ensuring that all actions are consistent with the International Health Regulations.

- APEC: At the November 2005 Asia Pacific Economic Cooperation (APEC) Summit, the United States supported APEC's Initiative to Prepare For and Mitigate an Influenza Pandemic to strengthen response and preparedness in the region, including through an inventory of regional disaster management capabilities, exercise of regional communications, and an Emerging Infectious Diseases Symposium in Beijing.
- GHSAG: Health Ministers from Canada, France, Germany, Italy, Japan, Mexico, United Kingdom, and the United States cooperate in the Global Health Security Action Group (GHSAG) to refine national pandemic influenza plans, support development of WHO protocols for early containment of influenza, and coordinate on capacity building in developing countries.
- G-8: The United States is encouraging the G-8 to support the development of an avian influenza plan and information packages for affected countries to use in the event of an outbreak, to agree on deployment of WHO stockpiles of antiviral medications and to adhere early to WHO's revised International Health Regulations.
- The United States is engaged with the private sector, including business groups like the APEC Business Advisory Council, the U.S.-Association of Southeast Asian Nations (ASEAN) Council, the American Chamber of Commerce, and the non-governmental community, on the role the private sector can play in preparing for and responding to a pandemic outbreak.



## Planning Assumptions

### Planning Assumptions for the Implementation Plan

Pandemics are unpredictable. While history offers useful benchmarks, there is no way to know the characteristics of a pandemic virus before it emerges. Nevertheless, we must make assumptions to facilitate planning efforts. Federal planning efforts assume the following:

1. Susceptibility to the pandemic influenza virus will be universal.
2. Efficient and sustained person-to-person transmission signals an imminent pandemic.
3. The clinical disease attack rate will be 30 percent in the overall population during the pandemic. Illness rates will be highest among school-aged children (about 40 percent) and decline with age. Among working adults, an average of 20 percent will become ill during a community outbreak.
4. Some persons will become infected but not develop clinically significant symptoms. Asymptomatic or minimally symptomatic individuals can transmit infection and develop immunity to subsequent infection.
5. While the number of patients seeking medical care cannot be predicted with certainty, in previous pandemics about half of those who became ill sought care. With the availability of effective antiviral medications for treatment, this proportion may be higher in the next pandemic.
6. Rates of serious illness, hospitalization, and deaths will depend on the virulence of the pandemic virus and differ by an order of magnitude between more and less severe scenarios. Risk groups for severe and fatal infection cannot be predicted with certainty but are likely to include infants, the elderly, pregnant women, and persons with chronic or immunosuppressive medical conditions.
7. Rates of absenteeism will depend on the severity of the pandemic. In a severe pandemic, absenteeism attributable to illness, the need to care for ill family members, and fear of infection may reach 40 percent during the peak weeks of a community outbreak, with lower rates of absenteeism during the weeks before and after the peak. Certain public health measures (closing schools, quarantining household contacts of infected individuals, “snow days”) are likely to increase rates of absenteeism.
8. The typical incubation period (interval between infection and onset of symptoms) for influenza is approximately 2 days.
9. Persons who become ill may shed virus and can transmit infection for one-half to one day before the onset of illness. Viral shedding and the risk of transmission will be greatest during the first 2 days of illness. Children will play a major role in transmission of infection as their illness rates are likely to be higher, they shed more virus over a longer period of time, and they control their secretions less well.
10. On average, infected persons will transmit infection to approximately two other people.
11. Epidemics will last 6 to 8 weeks in affected communities.
12. Multiple waves (periods during which community outbreaks occur across the country) of illness are likely to occur with each wave lasting 2 to 3 months. Historically, the largest waves have occurred in the fall and winter, but the seasonality of a pandemic cannot be predicted with certainty.

## CHAPTER 3 — FEDERAL GOVERNMENT RESPONSE TO A PANDEMIC

While the Implementation Plan (Plan) directs Federal departments and agencies to take action to prepare for a pandemic, it is important for the Federal Government to coordinate closely its efforts to gather relevant data and overall situational awareness in a timely manner from the initial phases of a pandemic until recovery is complete, and to communicate its approach to its international partners, State, local, and tribal entities, critical infrastructure owners and operators, and the public. This section describes the manner in which the Federal Government will coordinate its actions, the specific roles and responsibilities of the various Federal departments and agencies, and the specific actions to be taken at stages before, during, and after the occurrence of the first wave of a pandemic in the United States.

### **Command, Control, and Coordination of the Federal Response**

A pandemic will differ from most natural or manmade disasters in nearly every respect. Unlike events that are discretely bounded in space or time, a pandemic will spread across the globe over the course of months or over a year, possibly in waves, and will affect communities of all sizes and compositions. The impact of a severe pandemic may be more comparable to that of a widespread economic crisis than to a hurricane, earthquake, or act of terrorism. It may present as a particularly severe influenza season, or it may overwhelm the health and medical infrastructure of cities and have secondary and tertiary impacts on the stability of institutions and the economy. These consequences are impossible to predict before a pandemic emerges because the biological characteristics of the virus and the impact of our interventions cannot be known in advance.

Similarly, the role of the Federal Government in a pandemic response will differ in many respects from its role in most other natural or manmade events. The distributed nature of a pandemic, as well as the sheer burden of disease across the Nation, means that the physical and material support States, localities, and tribal entities can expect from the Federal Government will be limited in comparison to the aid it mobilizes for geographically and temporally bounded disasters like earthquakes or hurricanes. Nevertheless, the Federal Government must maintain complete situational awareness and be ready and able to take decisive action to ensure a comprehensive and timely national response to a pandemic. The Federal Government will also bear primary responsibility for certain critical functions, including the support of containment efforts overseas and limitation of the arrival of a pandemic to our shores; provision of clear guidance to State, local, and tribal entities, the private sector and the public on protective measures and responses that should be taken; modifications to the law and regulations to facilitate the national pandemic response; modifications to monetary policy to mitigate the economic impact of a pandemic on communities and the Nation; and many others. The Federal Government will also work to ensure the production and distribution of vaccine and antiviral medications to State, local, and tribal entities, and the acceleration of research, development, testing, and evaluation of vaccines and therapies during the outbreak.

To ensure an effective response, single points of contact within each State and Tribal Nation for the key functional areas of pandemic response will be identified. The Department of Homeland Security (DHS) will solicit from Governors and Tribal Chief Executive Officers a single point of contact within each State and Tribal Nation for overall incident management of pandemic influenza response efforts. The Department of Health and Human Services (HHS) will solicit lead points of contact for public health

and medical emergency response activities, and the Department of Agriculture (USDA) will solicit lead points of contact for veterinary response activities. DHS will coordinate the consolidation of these points of contact.

States, localities, and tribal entities across the Nation will each have to address the medical and non-medical impacts of the pandemic with available resources. This means that it is essential for State, local, and tribal entities to have plans in place to support the full spectrum of societal needs over the course of weeks or months, and for the Federal Government to provide clear guidance on the manner in which these needs can be met.

It is important that the Federal Government have a defined mechanism for coordination of its response. *The National Response Plan* (NRP) is the primary mechanism for coordination of the Federal Government response to terrorist attacks, major disasters, and other emergencies, and will form the basis of the Federal pandemic response. It defines Federal departmental responsibilities for sector-specific responses, and provides the structure and mechanisms for effective coordination among Federal, State, local, and tribal entities, the private sector, and non-governmental organizations (NGOs). Pursuant to the NRP and Homeland Security Presidential Directive 5 (HSPD-5), the Secretary of Homeland Security is responsible for coordination of Federal operations and resources, establishment of reporting requirements, and conduct of ongoing communications with Federal, State, local, and tribal governments, the private sector, and NGOs.

A pandemic will present unique challenges to the coordination of the U.S. Government response. First and foremost, the types of support that the Federal Government will provide to the Nation are of a different kind and character than those it traditionally provides to communities damaged by natural disasters. Second, although it may occur in discrete waves in any one locale, the national impact of a pandemic could last for many months. Finally, a pandemic is a sustained public health and medical emergency that will have sustained and profound consequences for the operation of critical infrastructure, the mobility of people and freight, and the global economy. Health and medical considerations will affect foreign policy, international trade and travel, domestic disease containment efforts, continuity of operations (COOP) within the Federal Government, and many other aspects of the Federal response.

Pursuant to the NRP, as the primary agency for, and coordinator for, Emergency Support Function #8 (Public Health and Medical Services), the Secretary of Health and Human Services will lead Federal health and medical response efforts and will be the principal Federal spokesperson for public health issues, coordinating closely with DHS on public messaging pertaining to the pandemic. Pursuant to HSPD-5, as the principal Federal official for domestic incident management, the Secretary of Homeland Security will provide coordination for Federal operations and resources, establish reporting requirements, and conduct ongoing communications with Federal, State, local, and tribal governments, the private sector, and NGOs. In the context of response to a pandemic, the Secretary of Homeland Security will coordinate overall non-medical support and response actions, and ensure necessary support to the Secretary of Health and Human Services' coordination of public health and medical emergency response efforts.

The NRP stipulates mechanisms for coordination of the Federal response, but sustaining these mechanisms for several months to over a year will present unique challenges. Day-to-day situational monitoring will occur through the national operations center, and strategic policy development and coordination on domestic pandemic response issues will be accomplished through an interagency body composed of senior decision makers from across the government and chaired by the White House. These and other considera-

tions applicable to response to a pandemic will be incorporated in the NRP review process and inform recommendations on revisions and improvements to the NRP and associated annexes.

Pursuant to the NRP, policy issues that cannot be resolved at the department level will be addressed through the Homeland Security Council/National Security Council (HSC/NSC)-led policy coordination process.

## **Roles and Responsibilities**

### **The Federal Government**

The *National Response Plan* is the primary mechanism for coordination of the Federal Government response to terrorist attacks, major disasters, and other emergencies, and will form the basis of the Federal pandemic response. While the Secretary of Homeland Security is responsible for overall coordination of Federal response actions for a pandemic, nothing in the NRP alters or impedes the ability of Federal, State, local, or tribal departments and agencies to carry out their specific authorities or perform their responsibilities under all applicable laws, Executive orders, and directives. Individual departments and agencies have responsibilities within the NRP for a pandemic, consistent with what is described below:

*The Secretary of Health and Human Services* will be responsible for the overall coordination of the public health and medical emergency response during a pandemic, to include coordination of all Federal medical support to communities; provision of guidance on infection control and treatment strategies to State, local, and tribal entities, and the public; maintenance, prioritization, and distribution of countermeasures in the Strategic National Stockpile; ongoing epidemiologic assessment, modeling of the outbreak, and research into the influenza virus, novel countermeasures, and rapid diagnostics.

*The Secretary of Homeland Security*, will be responsible for coordination of the Federal response as provided by the *National Strategy for Pandemic Influenza (Strategy)*, the Homeland Security Act of 2002, and HSPD-5, and will support the Secretary of Health and Human Services' coordination of overall public health and medical emergency response efforts. The Secretary will be responsible for coordination of the overall response to the pandemic, implementation of policies that facilitate compliance with recommended social distancing measures, the provision of a common operating picture for all departments and agencies of the Federal Government, and ensuring the integrity of the Nation's infrastructure, domestic security, and entry and exit screening for influenza at the borders.

*The Secretary of State* will be responsible for the coordination of the international response, including ensuring that other nations join us in our efforts to contain or slow the spread of a pandemic virus, helping to limit the adverse impacts on trade and commerce, and coordinating our efforts to assist other nations that are impacted by the pandemic.

*The Secretary of Defense* will be responsible for protecting American interests at home and abroad. The Secretary of Defense may assist in the support of domestic infrastructure and essential government services or, at the direction of the President and in coordination with the Attorney General, the maintenance of civil order or law enforcement, in accordance with applicable law. The Secretary of Defense will retain command of military forces providing support.

*The Secretary of Transportation* will be responsible for coordination of the transportation sector and will work to ensure that appropriate coordinated actions are taken by the sector to limit spread of infection while preserving the movement of essential goods and services and limiting the impact of the pandemic on the economy.

*The Secretary of Agriculture* will be responsible for overall coordination of veterinary response to a domestic animal outbreak of a pandemic virus or virus with pandemic potential and ongoing surveillance for influenza in domestic animals and animal products. The Secretary of Agriculture will also be responsible for ensuring that the Nation's commercial supply of meat, poultry, and egg products are wholesome, not adulterated, and properly labeled and packaged.

*The Secretary of the Treasury* will be responsible for monitoring and evaluating the economic impacts of the pandemic and will help formulate the economic policy response and advise on the likely economic impacts of containment efforts. The Secretary of the Treasury will also be responsible for preparing policy responses to pandemic-related international economic developments, for example, leading the Federal Government's engagement with the multilateral development banks (MDB) and international financial institutions (IFI), including encouraging MDB and IFI efforts to assist countries to address the impact of pandemic influenza.

The Secretary of Labor will be responsible for promoting the health, safety, and welfare of employees and tracking changes in employment, prices, and other economic measurements.

*Other Cabinet heads* will retain responsibility for their respective sectors. All departments and agencies will be responsible for developing pandemic plans that (1) provide for the health and safety of their employees; (2) ensure that the department or agency will be able to maintain its essential functions and services in the face of significant and sustained absenteeism; (3) provide clear direction on the manner in which the department will execute its responsibilities in support of the Federal response to a pandemic as described in this Plan; and (4) communicate pandemic preparedness and response guidance to all stakeholders of the department or agency.

### **Non-Federal Entities**

The *Strategy* and this Plan clearly articulate expectations for all stakeholders for pandemic preparedness and response, including international partners, State, local, and tribal entities, the private sector and infrastructure providers, and individuals and families. These expectations can be found under "Roles and Responsibilities" in the subsequent chapters and the "Actions and Expectations" contained at the end of each chapter.

## **Federal Government Actions during a Pandemic**

While the majority of this Plan describes specific actions that will be taken to improve our preparedness, it is important to show how this preparedness will translate to action in the period of time immediately before, during, and after the emergence of a pandemic. The unpredictable nature of a pandemic, the character of the pandemic virus, and the state of our preparedness efforts when a pandemic begins make it difficult to accurately predict all actions that the Federal Government will take during a pandemic. Nevertheless, it is possible to describe what action would be taken if a pandemic begins tomorrow, recognizing that our preparedness and ability to respond will improve with each passing month.

For containment to be effective, the United States and the international community must develop a comprehensive containment strategy that involves commitments of funding, supplies, equipment, training, expertise, personnel, countermeasures (e.g., antiviral medications, vaccine, and personal protective equipment (PPE)), and animal and public health measures in a coordinated, global approach. The success of such an effort, however, will be highly dependent on early notification of influenza cases, in

both humans and animals, caused by strains that have pandemic potential. Countries must immediately notify the World Health Organization (WHO) of such infections in humans, and the World Organization for Animal Health (OIE) for infections in animals, and provide timely sharing of samples to allow for an international response to be initiated.

### **World Health Organization Phases of a Pandemic**

It is most appropriate to link our actions to the phases of a pandemic. The WHO has defined six phases, before and during a pandemic, that are linked to the characteristics of a new influenza virus and its spread through the population. This characterization represents a useful starting point for discussion about Federal Government actions.

#### **Inter-Pandemic Period** (period of time between pandemics)

*Phase 1:* No new influenza virus subtypes have been detected in humans. An influenza virus subtype that has caused human infection may be present in animals. If present in animals, the risk of human disease is considered to be low.

*Phase 2:* No new influenza virus subtypes have been detected in humans. However, a circulating animal influenza virus subtype poses a substantial risk of human disease.

#### **Pandemic Alert Period**

*Phase 3:* Human infection(s) with a new subtype, but no human-to-human spread, or at most rare instances of spread to a close contact.

*Phase 4:* Small cluster(s) with limited human-to-human transmission but spread is highly localized, suggesting that the virus is not well adapted to humans.

*Phase 5:* Larger cluster(s) but human-to-human spread still localized, suggesting that the virus is becoming increasingly better adapted to humans, but may not yet be fully transmissible (substantial pandemic risk).

#### **Pandemic Period**

*Phase 6:* Pandemic phase: increased and sustained transmission in general population.

We are currently in WHO Phase 3 of the Pandemic Alert Period. As previously described, significant action is underway to prepare for a pandemic. It is the policy of the Federal Government to accelerate these preparedness efforts prior to WHO Phase 4, then initiate pandemic response actions at Phase 4, when epidemiological evidence of two generations of human-to-human transmission of a new influenza virus is documented anywhere in the world.

### **Stages of the Federal Government Response**

The WHO phases provide succinct statements about the global risk for a pandemic and provide benchmarks against which to measure global response capabilities. In order to describe the Federal Government approach to the pandemic response, however, it is more useful to characterize the stages of an outbreak in terms of the immediate and specific threat a pandemic virus poses to the U.S. population



(See *WHO Global Pandemic Phases and the Stages for Federal Government Response* between Chapters 5 and 6). The following stages provide a framework for Federal Government actions:

*Stage 0: New Domestic Animal Outbreak in At-Risk Country*

*Stage 1: Suspected Human Outbreak Overseas*

*Stage 2: Confirmed Human Outbreak Overseas*

*Stage 3: Widespread Human Outbreaks in Multiple Locations Overseas*

*Stage 4: First Human Case in North America*

*Stage 5: Spread throughout United States*

*Stage 6: Recovery and Preparation for Subsequent Waves*

The following description of the Federal Government response at each of these stages is divided into objectives, actions, policy decisions, and messaging considerations (see *Stages of Federal Government Response* between Chapters 5 and 6). “Immediate Actions” reflect those agreed-upon measures that would be triggered as each landmark for increasing risk to the U.S. population was passed. “Policy Decisions” reflect issues that would have to be considered by the Federal Government at the time, in the context of the available information about the pandemic and the status of our response. Finally, “Communications and Outreach” describes the high-level objectives of the guidance that is provided to the public; institutions; State, local, and tribal authorities; and our international partners.

This Plan will be updated on a regular basis to reflect ongoing policy decisions, as well as improvements in domestic preparedness (e.g., increases in the size of our domestic stockpile or vaccine production capacity).

The list of decisions and actions is not exhaustive—it is intended to provide a high-level overview of the Federal Government approach to a pandemic response. It should also be recognized that during a pandemic a number of actions and decisions will proceed in the face of incomplete information, or in the setting of a rapidly evolving epidemiologic or societal picture. It will be important to maintain a flexible and nimble response posture throughout the response, and adjust our approach as additional situational information becomes available. Finally, there are a series of crosscutting actions that will occur throughout the response. We will continuously review, reassess, and adjust our strategy as new information or response capabilities become available, in areas such as risk communication to the public, our allocation scheme for countermeasures, and the support provided to different sectors of critical infrastructure and the economy.

While this set of actions and decisions represents the Federal Government approach to the pandemic response, this approach will not be taken in a vacuum. We will ensure that our response is closely coordinated with our international partners, multilateral organizations, and State, local, and tribal entities, and that we provide clear, accurate, credible, and timely information about our response to the public and all other stakeholders on an ongoing basis.

## Summary of Federal Government Actions during a Pandemic

### Stage 0: New Domestic Animal Outbreak in At-Risk Country (WHO Phase 1, 2, or 3)

A human pandemic influenza virus could emerge outside the United States or within our borders. Because of the potential for an HPAI virus, including the current HPAI H5N1, to become a pandemic strain, many international animal health initiatives are being implemented to assist affected countries with their response to disease outbreaks in poultry. Control of threatening viruses among animals is a critical element of the strategy to reduce the level of human exposure, a key risk factor for infection and, therefore, emergence of a pandemic strain.

Regardless of where the risk exists for emergence of a pandemic strain, we must be prepared to respond appropriately. A robust surveillance system in domestic animals and wildlife is required to ensure detection and identify new outbreaks in previously unaffected countries. Of the two, outbreaks in domestic animals present a relatively higher likelihood of human exposure to influenza virus than do outbreaks in wildlife. Domestic animal infections may also present more opportunity than do wildlife infections for an influenza virus to undergo genetic reassortment and become a human pandemic strain. This means that when an influenza virus with human pandemic potential is introduced into domestic birds or other domestic animals in a previously unaffected country, the infection must be detected and eradicated as quickly as possible. If such a virus is found in wild birds or other wildlife, efforts should be directed at preventing it from being introduced into domestic birds or other susceptible animals.

Perhaps most importantly, surveillance of animals needs to be integrated with human influenza surveillance activities at a national level. It is important for results of animal surveillance to serve as an input that may help target human surveillance efforts, relative to temporal, geographic, or other risk factors, especially when an influenza virus with human pandemic potential is detected in birds or other animals.

A confirmed outbreak in domestic animals of an influenza virus with pandemic potential, especially one that has already shown the ability to cause illness in humans, signals an important opportunity to decrease the risk of a human pandemic. When such an outbreak occurs in a country that is not currently experiencing other outbreaks caused by that strain of influenza virus, there will be a variety of actions that need to be taken to address the situation. It is incumbent upon the international community to take rapid action to ascertain the facts on the ground and provide appropriate assistance to the affected country. The steps taken in this stage will be closely coordinated with our international partners and multilateral organizations such as the United Nations Food and Agriculture Organization (FAO) and the OIE.

Should such an outbreak occur within the United States, appropriate response and coordination activities will be initiated as presented in Chapter 7 — Protecting Animal Health.

#### Objectives

- Track outbreaks until control/resolution.
- Provide coordination mechanisms, logistical support, and technical guidance.
- Monitor for reoccurrence of disease.



**Immediate Actions**

- Initiate dialogue with FAO, other relevant international health organizations, and other international partners to ensure complete coordinated support (Department of State (DOS) and USDA).
- Initiate dialogue with affected nation through diplomatic, animal health, and human health channels to ascertain situation, offer scientific, technical, and, potentially, economic and trade assistance, and encourage full and open sharing of information (DOS, HHS, and USDA).
- Prepare to deploy rapid response team including influenza epidemiology, diagnostics, public-health management, and communications, as part of bilateral and multilateral teams to assess situation and requirements for successful animal disease eradication and human disease prevention effort (DOS, USDA, U.S. Agency for International Development (USAID), Department of Defense (DOD), and HHS).
- Prepare to supply testing protocols and deploy reagents and equipment to support diagnostic requirements for both animal and human testing (USDA, HHS, DOD, and DHS).
- Prepare to deploy animal disease response materiel, including PPE (USDA and USAID).

**Policy Decisions**

- Deployment of countermeasures to affected country as part of the U.S. contribution to an animal disease control and eradication effort.

**Communications and Outreach**

- All: Advise that the Federal Government, along with international partners, is working to ascertain situation as quickly as possible, and that information will be communicated as it becomes available.
- International: Encourage nations and international animal and public health organizations to engage in rapid, coordinated assessments and coordinated communication of findings.
- Public: Reassure public that disease containment measures have been implemented and indicate that measures are targeted at preventing animal-to-animal and animal-to-human transmission.

**Stage 1: Suspected Human Outbreak Overseas (WHO Phase 3)**

There are many ways in which suspicious clusters of illness may come to our attention, including through reporting to the WHO, news reporting, clinical results in regional laboratories, or through word of mouth or other informal channels. It is incumbent upon the international community to take rapid action to ascertain the facts on the ground, irrespective of the manner in which the reporting occurs. The steps taken here and at subsequent stages will be closely coordinated with our international partners and multilateral organizations such as the WHO.

With the WHO Secretariat and other partners, countries should agree ahead of time on the core content of basic information packages that will be necessary to give to the public in the event of a pandemic, and, to the greatest extent possible, develop an agreed “script” of common, harmonized messages to broadcast

to the public immediately and continuing for at least 36 to 48 hours after a pandemic has potentially begun.

### **Objectives**

- Rapidly investigate and confirm or refute reports of human-to-human transmission.
- Initiate coordination mechanisms and logistical support that will be necessary if outbreak confirmed.

### **Immediate Actions**

- Initiate dialogue with WHO and other relevant international health organizations to ensure complete coordinated support (DOS and HHS).
- Deploy rapid response team including influenza epidemiology, microbiology, public health management, infection control, and communications, as part of bilateral and multilateral teams to assess situation and identify situation-specific requirements for successful containment effort if human-to-human transmission strongly suspected or confirmed (HHS).
- Ensure rapid genetic sequencing of viral isolates is performed, providing U.S. facilities and resources to support sequencing and comparison with existing influenza gene libraries as needed (HHS).
- Activate logistical capability to transport samples to the United States or other key locations (HHS and DOD).
- Prepare to deploy reagents to support surge diagnostic requirements (HHS).
- Amplify laboratory-based and clinical surveillance in region (DOD and HHS).
- Prepare to provide logistical support for deployment of stockpile materiel to region, including identification of necessary equipment, supplies, and personnel (DOD and HHS).
- Activate Assistant Secretary-level task force to track developments in region, coordinate and communicate information flow across interagency, and coordinate response efforts and decisions (DOS, HHS, and DHS).
- Initiate dialogue with potentially affected nations through diplomatic and health channels to ascertain situation, offer scientific, technical, and potentially economic and trade assistance, and encourage full and open sharing of information; initiate dialogue with international partners to ensure complete coordinated support (DOS and HHS).
- Review domestic plans to increase layered protective measures at borders and prepare to implement travel restrictions from affected areas, as appropriate (DHS, HHS, and Department of Transportation (DOT)).

### **Policy Decisions**

- Pre-positioning of U.S. contribution to international stockpile assets in region of suspected outbreak.

The *Pandemic Stages* section of this document have been updated. See [MMWR: Vol. 63/No. 6 \(09-26-2014\)](#).

- Vaccination of selected populations with pre-pandemic vaccine.

#### **Communications and Outreach**

- All: Advise that the Federal Government, along with international partners, is working to ascertain situation as quickly as possible, and that information will be communicated as it becomes available.
- International: Encourage nations and international organizations to engage in rapid, coordinated assessments and coordinated communication of findings.
- State/local/tribal entities and Institutions: Review pandemic plans and direct to trusted information sources such as **www.pandemicflu.gov**.
- Public: Reassure public, explain confirmed facts, and direct to trusted information sources such as **www.pandemicflu.gov**.

#### **Stage 2: Confirmed Human Outbreak Overseas (WHO Phase 4 or 5)**

We will rely upon the WHO to confirm sustained human-to-human transmission of a novel influenza virus, but it is possible that confirmation will come directly from an affected nation or through our own scientists in the affected region.

#### **Objectives**

- Contain the outbreak to the affected region(s) and limit potential for spread to the United States.
- Activate the domestic public health and medical response.

#### **Immediate Actions**

- Deploy non-countermeasure components of international stockpile and diagnostic reagents to support outbreak investigation, as well as technical and medical assistance (DOS, HHS, and DOD).
- Rapidly assess conditions and likelihood of international containment or slowing of pandemic spread (HHS, DHS, DOD, and DOS).
- Support international deployment of countermeasures to affected region(s) (see below).
- Work with other countries to implement host country pre-departure screening and initiate U.S. en route and arrival screening at U.S. ports of entry (DOS, DOT, DHS, HHS, and DOD).
- Consider travel or routing restrictions from the affected area and for countries that do not have adequate pre-departure screening (DHS, DOT, DOS, and DOD).
- Implement protocols for cargo handling that allow trade to continue, when possible (DHS, DOD, DOS, and DOT).

- Implement protocols to manage or divert inbound international flights with suspected cases of pandemic influenza and prepare to limit domestic ports of entry to manage increased demand for screening, as needed (DOT, DOS, DHS, HHS, and DOD).
- Activate domestic quarantine stations and ensure coordination at State, local, and tribal level, especially with health care resources (HHS and DHS).
- Declare Incident of National Significance (DHS in coordination with other Federal departments).
- Amplify hospital-based surveillance in all communities (HHS).
- Develop seed for vaccine and prepare to produce monovalent vaccine (HHS).
- Meet with vaccine and pharmaceutical manufacturers to discuss maximal exploitation of production capacity and regulatory modifications to facilitate countermeasure production (HHS).
- Develop, produce, and deploy diagnostic reagents for pandemic virus to Laboratory Response Network (LRN) laboratories (HHS).
- Prepare to provide military bases and installation support to Federal, State, local, and tribal agencies (DOD).
- Evaluate ability of pandemic virus to infect and replicate efficiently in poultry or other animals and take appropriate actions based on the results of the evaluation (USDA).
- Determine whether pre-pandemic vaccine is effective against pandemic strain (HHS).
- Review domestic pandemic plans and prepare for response, placing critical staff on recall and pre-deploying assets where appropriate (All).

### **Policy Decisions**

- Deployment of countermeasures to affected region(s) as part of the U.S. contribution to a containment effort.
- Entry/exit screening criteria, nations/regions involved, protocol for isolation and quarantine of passengers and employees.
- Diversion of annual trivalent vaccine production to monovalent pandemic vaccine when seed virus available.
- Pre-vaccination with or administration of a primer dose of pre-pandemic (unmatched) vaccine for emergency response teams (to be followed by pandemic strain vaccine, when available).
- Revision of prioritization and allocation scheme for pandemic vaccine and antiviral medications, based upon real-time situational analysis of characteristics of the pandemic virus, epidemiological analyses, and the most recent data regarding available stockpiles of countermeasures.

- Deployment of pre-pandemic vaccine to State/tribal entities and to Federal departments and agencies, and initiation of vaccination.

#### **Communications and Outreach**

- All: Place all on alert that a high likelihood of a pandemic exists, educate all stakeholders on Federal Government response and containment strategies and expectations for all entities below.
- International: Encourage rapid, coordinated containment effort and coordinated actions to limit from region and to screen passengers.
- State/local/tribal: Place on alert for spread of outbreak to the United States; activate preparedness/response plans and surveillance systems; initiate regular calls with Governors and State/tribal public health and emergency preparedness leaders to provide guidance on preparedness actions necessary and to coordinate messaging.
- Institutions: Make organizations aware of continuity plans and measures to limit infection transmission in workplace; reassure that efforts will be made to limit adverse impact on movement of goods, services and people.
- Public: Prepare public for possibility of a pandemic while providing information about containment efforts, reassure that we have not yet seen cases domestically; review actions that reduce likelihood of influenza exposure and limit influenza transmission.

### **Stage 3: Widespread Human Outbreaks in Multiple Locations Overseas (WHO Phase 6)**

The occurrence of widespread outbreaks suggests that efforts are unlikely to be successful in containing the emerging pandemic. We will focus our efforts on our domestic preparedness posture and response actions and on delaying the onset of epidemics within the United States.

#### **Objectives**

- Delay the emergence of pandemic influenza in the U.S. and North American populations.
- Ensure the earliest warning possible of the first case(s) in North America.
- Prepare our domestic containment and response mechanisms.

#### **Immediate Actions**

- Re-examine limitation on international travel from affected regions (or regions that do not institute pre-departure screening) and maintain layered screening measures for host country pre-departure, en route, and arrival of U.S.-bound travelers (DOS, DHS, and HHS).
- Prepare “containment stockpile” for deployment to quarantine stations and other locations as appropriate (HHS).
- Maintain heightened hospital-based surveillance in all communities (HHS).

- If not previously available, develop and deploy diagnostic reagents for pandemic virus to all LRN laboratories (HHS).
- Perform real-time modeling and epidemiological analyses to characterize the virus, its speed of spread, and impact on the population to inform recommendations concerning public health interventions and countermeasure prioritization (HHS).
- Deploy antiviral stockpile with appropriate security to State/tribal entities and to Federal departments and agencies, with prioritization and treatment recommendations (HHS).
- Prepare to implement surge plans at Federal medical facilities (HHS, DOD and Department of Veterans Affairs (VA)).
- Activate domestic emergency medical personnel plans (HHS and VA).
- If not previously done, divert annual trivalent vaccine production to monovalent pandemic vaccine (HHS).
- Deploy pre-pandemic vaccine to State/tribal entities and to Federal agencies, and initiation of vaccination.

#### **Policy Decisions**

- Prioritize efforts for domestic preparedness and response.

#### **Communications and Outreach**

- International: Reinforce importance of limiting travel in affected areas and continuing entry/exit screening.
- State/local/tribal: Advise governments to activate pandemic response plans; review influenza case definition and testing protocols used by public health and medical community; announce preliminary conclusions of epidemiologic assessments and modeling; request that State, local, and tribal leadership reach out to critical infrastructure providers to ensure that continuity plans are in place.
- Institutions: Review COOP guidance.
- Public: Review preparedness and countermeasure distribution guidance; advise public to prepare to reduce non-essential domestic travel once epidemic reaches United States.

#### **Stage 4: First Human Case in North America (WHO Phase 6)**

We recognize that the development of the first case anywhere in North America represents a significant threat to the entire continent, as for practical purposes it will be impossible to prevent completely the migration of disease across land borders. We also recognize that a pandemic could originate in North America, rather than overseas, in which case our response would begin with the steps below. We will work with Canada and Mexico to delay the spread of the pandemic across North America through aggressive attempts to contain the initial North American outbreaks, recognizing the challenges associated with such an effort.

**Objectives**

- Contain the first cases on the continent with slowing of first and subsequent pandemic waves of spread.
- Antiviral treatment and prophylaxis.
- Implement the national response.

**Immediate Actions**

- Deploy “containment stockpile,” if available, to any domestic region with confirmed or suspected cases of pandemic influenza, if an epidemiologic link to an affected region exists (HHS).
- Limit non-essential passenger travel in affected areas and institute protective measures/social distancing, and support continued delivery of essential goods and services (DHS, DOT, and HHS).
- Ensure that pandemic plans are activated across all levels of government and in all institutions (HHS and DHS).
- Continue with development of pandemic vaccine (HHS).
- Activate surge plans within Federal health care systems and request that State, local, and tribal entities do the same (HHS and DHS).
- Continue to develop and deploy diagnostic reagents for pandemic virus to all LRN laboratories and other laboratories with capability and expertise in pandemic influenza diagnostic testing (HHS).
- Antiviral treatment and targeted antiviral prophylaxis (HHS).

**Policy Decisions**

- Revision of prioritization and allocation scheme for pandemic vaccine as appropriate, based upon characteristics of the pandemic virus and available quantities of vaccine.

**Communications and Outreach**

- All: Communicate up-to-date information on epidemiologic characteristics of virus and outbreak modeling.
- International: Reinforce importance of travel restrictions and entry/exit screening.
- State/local/tribal: Advise State, local, and tribal leadership to implement pandemic response plans; provide guidance on public communication.
- Institutions: Advise institutions to implement continuity plans.
- Public: Review actions that reduce likelihood of influenza exposure and limit influenza transmission; assure public of ability to maintain domestic safety and security; advise public to

*The Pandemic Stages section of this document have been updated. See [MMWR: Vol. 63/No. 6 \(09-26-2014\)](#).*

curtail non-essential travel and prepare for implementation of community disease containment measures as epidemic spreads (See *Individual, Family, and Community Response to Pandemic Influenza* between chapters 5 and 6).

#### **Stage 5: Spread throughout United States (WHO Phase 6)**

The emergence of human cases in multiple locations around the country will portend a progressive increase in case load on communities and a resulting impact on all institutions, including those supporting critical infrastructure.

##### **Objectives**

- Support community responses to the extent possible to mitigate illness, suffering, and death.
- Preserve the functioning of critical infrastructure and mitigate impact to the economy and functioning of society.

##### **Immediate Actions**

- Maintain continuous situational awareness of community needs, triage, and direct Federal support of health and medical systems, infrastructure, and maintenance of civil order as feasible (All).
- Deploy pandemic vaccine, if available, with continuously updated guidance on prioritization and use (HHS).
- Continuously evaluate the epidemiology of the pandemic virus and update recommendations on treatment of patients and protective actions for all sectors on an ongoing basis (HHS and DHS).
- Provide guidance on judicious use of key commodities to reduce the likelihood of shortages (DHS).

##### **Policy Decisions**

- Determination of whether (and if so, the form of) Federal intervention is required to support critical infrastructure and the availability of key goods and services (such as food, utilities, and medical supplies and services).
- Determination of when travel restrictions previously enacted can be lifted.

##### **Communications and Outreach**

- International: Advise that the United States is executing its plans to assure continuity of society and national defense.
- State/local/tribal entities and Institutions: Advise that Federal Government will continue to provide support, as possible; advise continued implementation of continuity plans, update guidance on epidemiology and successful COOP plans.



- Public: Review actions that reduce likelihood of influenza exposure and limit influenza transmission; provide candid messages about the epidemiology of the virus, the likelihood of contracting influenza and likelihood of severe illness.

#### **Stage 6: Recovery and Preparation for Subsequent Waves (WHO Phase 6 or 5)**

While a pandemic may impact the Nation for several months or over a year, a given community can expect to be affected by a pandemic over the course of 6 to 8 weeks. While subsequent waves have been the norm in previous pandemics, it will be important for communities to begin reconstituting themselves as soon as possible in order to mitigate persistent secondary and tertiary impacts of the outbreak, including the adverse economic consequences that are anticipated.

##### **Objectives**

- Return all sectors to a pre-pandemic level of functioning as soon as possible.
- Prepare for subsequent waves of pandemic.

##### **Immediate Actions**

- Work with private sector, State, local, and tribal entities to prioritize and begin restoring essential services and reviewing plans to maintain continuity of operations in subsequent waves with support of employees that are immunized or have developed immunity (DHS and HHS).
- Redeploy and refit Federal response assets (All).
- Resume essential Federal functions and ensure continuity of operation through subsequent waves (DHS and All).
- Maintain continuous situational awareness of disease in communities, in order to forecast the reduction in illness and reduction in strain on critical infrastructure (HHS and DHS).
- Provide continuously updated information about the epidemiology of the virus, effective treatments, and lessons learned from the first wave, so as to enhance preparedness for subsequent waves (HHS).
- Continue deployment of pandemic vaccine in preparation for subsequent waves (HHS).
- Review lessons learned to develop strategies for subsequent waves (All).

##### **Policy Decisions**

- Determination as to whether Federal support is needed for any sector(s) unable to function effectively after the pandemic.

##### **Communications and Outreach**

- All: Advise that additional waves of the pandemic may occur and emphasize need to prepare accordingly; communicate key lessons learned to all sectors, and recommend actions to enhance preparedness for subsequent waves.

## CHAPTER 4 — INTERNATIONAL EFFORTS

### Introduction

Pandemic influenza is a global threat. Given the rapid speed of transmission, the universal susceptibility of human populations, and even a modest degree of lethality, an outbreak of pandemic influenza anywhere poses a risk to populations everywhere. Our international effort to contain and mitigate the effects of an outbreak of pandemic influenza beyond our borders is a central component of our strategy to stop, slow, or limit the spread of infection to the United States.

To meet this important international challenge, all nations and the broader international community must be able to detect and respond rapidly to outbreaks of animal or human influenza with pandemic potential to contain the infection and delay its spread. Many countries, however, do not have sufficient resources or expertise to detect and respond to outbreaks independently. International mechanisms to support effective global surveillance and response, including coordinated provision of accurate and timely information to the public, are also inadequate.

For these reasons, through the International Partnership on Avian and Pandemic Influenza (the Partnership), established by President George W. Bush in September 2005, and other bilateral and multi-lateral international engagement, the Federal Government is heightening awareness of the threat on the part of foreign governments and publics, and promoting development of national and international capacity and commitment to prevent, detect, and limit the spread of animal and human pandemic influenza within and beyond national borders. We are elevating pandemic influenza on national agendas, coordinating efforts among donor and affected nations, mobilizing and leveraging global resources, increasing transparency in global disease reporting and surveillance, and building global public health capacity. The United States is also offering bilateral assistance to strengthen capacity to fight pandemic influenza in the countries at highest risk.

### Key Considerations

With the ever-present threat that a newly emerging strain of animal influenza could spark a human pandemic, it is essential that highly pathogenic viruses in animals, wherever they appear, be carefully monitored for changes that could indicate an elevated threat to humans. An outbreak of a novel strain or subtype of influenza capable of sustained and efficient human-to-human transmission, which could occur in the United States or abroad, would spread quickly within an affected community, doubling in size approximately every 3 days. Thorough preparedness, robust surveillance, and strong response on the part of all countries are critically important, as the probability of containing an outbreak of a pandemic virus at its site of origin depends on how quickly a country detects and reports it, shares and tests viral samples, distributes effective countermeasures, and implements public health measures to limit spread.

There are significant challenges to a rapid response to an incipient human pandemic in many countries at risk. The threat of pandemic influenza may not be widely recognized or understood. Many countries at risk lack robust public health and communications infrastructure, pandemic preparedness plans, and proven logistics capability. In many developing countries the livelihood of families is linked to the animals they own, and reporting an outbreak of animal influenza can result in the destruction of a family's animals and, therefore, a threat to their livelihood. Lack of infrastructure and expertise to detect

an outbreak in a remote location and quickly transport a sample to a laboratory with appropriate diagnostic capability can impede timely and effective application of countermeasures. Many countries at risk also do not have the veterinary, medical, and non-medical countermeasures, including antiviral medications, to contain a confirmed outbreak.

To promote an effective global response to a pandemic outbreak, donor countries and relevant international health organizations should assist countries that have less capacity and expertise as well as fewer of the necessary resources.

### **Limited International Capacity**

In many of the countries in which the risk of emergence of pandemic influenza is considered to be high, the animal and human health sectors lack the expertise, resources, and infrastructure necessary to effectively detect and contain animal cases and prevent human cases. Recent outbreaks of avian influenza in Asia, Europe, and Africa highlight critical shortcomings in national human and animal disease surveillance and reporting. Early warning and clinical surveillance systems are insufficient to detect changes in an influenza virus that could lead to emergence of a pandemic strain. Key gaps include lack of understanding of the nature of the threat and ways to prevent it, scarcity of well-trained laboratory, epidemiologic, medical, and veterinary staff to provide effective in-country surveillance, and the need for greater commitment and capacity to share data, specimens, and viral isolates rapidly and transparently with national and international animal and human health authorities. International animal and human health mechanisms and resources also need to be strengthened.

Because the risk to public health from an animal influenza virus with human pandemic potential is directly related to the ability to detect and control such viruses in animal populations, the effectiveness of national veterinary services of affected, high-risk, and at-risk countries is critical to minimize human exposure to threatening animal viruses. The objective of controlling or eliminating an animal influenza virus with pandemic potential can only be attained, and then maintained, through concurrent strengthening of national veterinary services. This will require international support for the development of sustainable veterinary services in affected, high-risk, and at-risk countries, and the domestic will of those countries to make such development a priority. Support for development should be based on a unified assessment approach that can be applied in a consistent manner to individual countries to help determine what must be done to create an adequate and sustainable animal health infrastructure.

Likewise, in many countries, limited capacity to detect and control outbreaks of respiratory diseases among humans also adversely impacts on international ability to detect and control the emergence of an influenza pandemic. Countries must give priority to strengthening their public health and respiratory disease case management capacities. The international community must support this prioritization in a consistent and coordinated manner.

As a key part of the U.S. Government's international efforts in support of the *National Strategy for Pandemic Influenza (Strategy)*, under the coordination of the Department of State (DOS) and the U.S. Agency for International Development (USAID), the Department of Health and Human Services (HHS), the Department of Agriculture (USDA), the Department of Homeland Security (DHS), the Department of Transportation (DOT), and the Department of Defense (DOD) are working in cooperation, through complementary strategies, to build capacity in countries at risk to address aspects of avian influenza related to human and animal health.

### *Preparedness and Planning*

Comprehensive preparation including the development and exercise of national and regional plans to respond to a pandemic will facilitate containment efforts and should help mitigate social impacts when containment fails. HHS, DOS, USAID, and USDA are working together to assist priority countries, especially those in which highly pathogenic H5N1 avian influenza is endemic or emerging, to develop, and exercise plans for effective response to a possible extended human pandemic outbreak. We also are supporting public education and risk communication on best practices to prevent and contain animal and human infection.

### *Surveillance and Response*

A country's ability to respond to a human outbreak quickly, requires a broad surveillance network to detect cases of influenza-like illnesses in people, coupled with rapid diagnostic and response capabilities. To help address these challenges, HHS and USAID, in collaboration with DOS, DOD, and international partners, will work together and with the WHO Influenza Network to assist countries at risk, including those that are experiencing outbreaks of H5N1 highly pathogenic avian influenza, to build and improve infrastructure at the central, provincial, and local levels to provide timely notification of suspected human cases of influenza with pandemic potential. Building this capability in countries at risk will facilitate monitoring of disease spread and rapid response to contain influenza outbreaks with pandemic potential. HHS, USAID, DHS, and DOS will support development of rapid response teams, coordinated logistics capability, and new modeling efforts to support containment; increase involvement of the private sector in prevention and control of animal influenza, pandemic planning, and risk management; and improve the ability of the health care sector to control infection and manage cases.

### *Donor Coordination*

To fully address the needs of countries at risk, increased assistance from other countries and international organizations is necessary. In addition, donors must coordinate international assistance resources and activities to avoid duplication of effort and maximize results. DOS, with relevant U.S. Government agencies, is working through the Partnership and other multilateral and bilateral diplomatic contacts to encourage increased, coordinated, international assistance. The United States also will intensify efforts to engage the private sector on the role it can play in preparing for and responding to a pandemic outbreak.

In our bilateral assistance efforts, the United States takes into account assistance pledged by other donors. We target bilateral assistance and expertise to build global veterinary and public health capacity in the countries we believe to be at highest risk, taking into account existing country capacities and needs, and the likelihood that U.S. Government funding will have an impact in a particular country or region given the disease situation, population size, and existing capacities and needs, which vary from country to country. U.S. assistance abroad is intended to protect the health of the American people abroad.

### *Strengthening International Animal Health Infrastructure*

To address needs related to developing sustainable animal health infrastructures in affected, high-risk, or at-risk countries, we will work with the World Organization for Animal Health (OIE), the United Nations (UN) Food and Agriculture Organization (FAO), and other members of the Partnership to develop a unified and consistent approach for such infrastructure development in all countries. The approach will include an assessment of needs for the reduction of animal influenza with human pandemic potential in countries where it exists, and of needs that individual countries may have in making the building of their

national veterinary services capacity a domestic priority. Potential options for funding to meet those needs will also be identified. The ultimate goal will be to implement a program through the OIE and FAO and other partners to develop stronger international coordination and support for the animal health response to the current H5N1 avian influenza outbreak in Asia, Europe, and Africa, and for prevention and containment of any future animal disease outbreaks of international concern or consequence.

### **Key Elements of Effective International Response and Containment**

To contain an outbreak of influenza with pandemic potential or delay its spread, a coordinated response by the international community in support of national efforts is key. Many affected countries or regions will require international assistance to detect cases early and respond quickly and effectively to prevent spread. Instituting countermeasures to prevent or slow the spread of infection, including exit and entry screening, restrictions on movement across borders, and rapid deployment of international stocks of antiviral medications, requires international preparation and coordination to be most effective. The U.S. Government is working with WHO, the Partnership, and through diplomatic contacts to strengthen international mechanisms to respond to an outbreak of influenza with pandemic potential, including finalization of WHO's doctrine of international response and containment which lays out the responsibilities of the international community and countries with human outbreaks, and includes provisions to develop and deploy critical resources needed to contain the virus. The U.S. Government considers the following to be key elements of an international response effort.

#### *Agreed Epidemiological "Trigger" for International Response and Containment*

While WHO has stated that the first potential signal of early pandemic activity cannot be known in advance and precise "triggering" activity cannot be fully developed ahead of time, WHO also has stated that containment will be strongly considered in the following circumstances:

- Moderate-to-severe respiratory illness (or deaths) in three or more health care workers who have no known exposure other than contact with ill patients, and laboratory confirmation of infection (novel influenza virus) in at least one of these workers.
- Moderate-to-severe respiratory illness (or deaths) in 5 to 10 persons with evidence of human-to-human transmission in at least some, and laboratory confirmation of infection (novel influenza virus) in more than two of these persons.
- Compelling evidence that more than one generation of human-to-human transmission of the virus has occurred.
- Isolation of a novel (influenza) virus combining avian and human genetic material or a virus with an increased number of mutations not seen in avian isolates from one or more persons with moderate-to-severe respiratory illness (acute onset), supported by epidemiological evidence that transmission patterns have changed.

The WHO also has stated that containment will not be attempted in any of the following circumstances:

- Laboratory studies fail to confirm infection caused by a novel influenza virus.
- The number or geographical distribution of affected persons is so large at time of detection that it renders containment impracticable for logistic reasons (i.e., the number of persons requiring prophylactic administration of antiviral drugs exceeds available supplies, or the size of the

affected community makes it impossible to ensure adequate supplies of food and shelter, and the provision of medical care and emergency services during a containment operation).

- More than 4 to 6 weeks have passed since detection of the initial cluster, thus decreasing the likelihood that containment would be successful.

The feasibility of rapid containment will further depend on the number of contacts of the initial cases and the ability of the government authorities and international teams to ensure basic infrastructure and essential services to the affected population. Such services include shelter, power, water, sanitation, food, security, and communications with the outside world.

With disease confirmation, the WHO Director-General would announce a human outbreak of an influenza virus with pandemic potential, after consultation with experts from HHS and scientists from other governments. As outlined above, the basis for announcing a human outbreak of pandemic potential would consider a number of factors, including the number of individuals affected, the rapidity of spread, and the virulence of the disease. An outbreak of an influenza virus with pandemic potential is considered a Public Health Emergency of International Concern under the revised International Health Regulations, adopted by the World Health Assembly in May 2005.

#### *Rapid, Transparent Reporting and Sharing of Samples*

Countries should immediately take certain actions in response to a suspected outbreak, including prompt reporting of the outbreak to the WHO Secretariat, sharing of viral isolates and/or tissue samples with WHO-designated laboratories for confirmation and vaccine development, activation of national response plans in an effort to contain the outbreak, implementation of public health measures including prophylaxis, vaccination, and social distancing measures (e.g., school closures, snow days, quarantines) in the affected area, epidemiological investigation to identify additional cases and pinpoint the source of the infection, and implementation of screening of passengers. The United States will work with the international community to develop capacity and resources to encourage these actions by countries and regions affected by human outbreaks.

#### *Rapid Response Teams*

The international community should develop international Rapid Response Teams to investigate and respond to the suspected beginning of a pandemic. The United States is identifying experts to commit to the teams and encouraging other countries with significant veterinary and public health capacity to do the same. The international community should encourage and assist the WHO Secretariat, the FAO, and the OIE to organize, train, equip, exercise, and deploy these teams.

#### *Stockpiles of Countermeasures*

Medical and non-medical countermeasures should be stockpiled and pre-positioned for rapid deployment to help ensure that countries affected by an outbreak of pandemic influenza can launch an effective effort to contain the incipient pandemic. The WHO Secretariat has called for the establishment of an international stockpile of medical countermeasures and the development of an agreed international plan to allocate and deploy them in the event of a pandemic outbreak. WHO is now working with health experts to determine the size, composition, and locations of stockpiles needed for a rapid and effective response and to develop a doctrine of deployment. The U.S. Government has identified medical countermeasures it is prepared to commit for deployment to the international stockpile when needed, and is



urging other countries to do the same. We also are supporting international efforts to stockpile non-medical countermeasures, both goods and services, to support containment of animal or human influenza outbreaks with pandemic potential, including transportation of personnel and materiel, personal protective equipment, screening and isolation equipment, disinfectants, temporary shelters, and technical and logistical resources needed to implement an effective containment response.

#### *Logistical Support for an International Response*

The international community needs to develop a plan and to identify resources to rapidly transport personnel, supplies and other materiel to support an international containment response, including in geographically remote or underdeveloped locations. The U.S. Government is determining its capabilities in this regard, and will encourage the international community to explore the logistical needs for a coordinated international response and how to address them.

#### **Surveillance to Limit Spread**

Early outbreak detection with continued surveillance of travelers and institution of appropriate measures, including social distancing, isolation of infected individuals, quarantine of suspected cases, or treatment with antiviral medications can help delay or limit the spread of a virus once a case occurs. Well-coordinated international implementation of entry and exit restrictions is an important component of an effective global response to contain cases and prevent a pandemic. All countries should prepare to implement steps to limit spread, including local, regional, and national entry and exit restrictions based on veterinary and health monitoring, screening and surveillance for humans, animals, and animal products, and information sharing and cooperation to manage borders. Recognizing the significant costs to implementing border restrictions and the need for international coordination to achieve maximum efficacy, the U.S. Government is examining which surveillance steps will be most effective in limiting spread, including pre-departure exit screening for travelers from affected areas, a reduction of the number of entry and exit points to the United States for international travelers, disease surveillance and entry screening at U.S. borders, and exit screening for travelers leaving the United States in the event of a case occurring here. The international community should provide technical assistance and support personnel to countries that need it to implement screening quickly and effectively. We will endeavor to establish agreements and arrangements with our international partners to ensure the international community takes coordinated action on screening, that such measures are tailored as narrowly as possible to be consistent with efficacy, and that they are lifted quickly when their utility has ended.

#### **Development of Vaccines and Rapid Diagnostics**

Vaccines when they become available will be a major means of controlling the spread of a pandemic and reducing associated mortality and morbidity. The vaccine industry, however, faces many risks and uncertainties, including unpredictable market demand and pricing, liability and intellectual property considerations, and regulatory and tax issues. As a result, global and domestic vaccine research and manufacturing capacity is limited. Strong public/private partnerships are needed among government, academia, and industry globally as well as nationally to build vaccine production capacity to levels necessary to address a pandemic and establish a reliable vaccine supply. In addition to its efforts to increase domestic vaccine production capacity, the United States is working through several programs to provide direct and indirect support to multinational vaccine manufacturers, foreign academic institutions, and foreign governments to increase global vaccine production capacity. HHS is supporting advanced development of cell-based influenza vaccines, the evaluation of new H5N1 vaccine candidates, and

development of global capacity to produce large quantities of pre-pandemic vaccine (i.e., a vaccine against human infection with the strain of influenza A (H5N1) that is currently circulating among poultry) on a commercial scale through the award of contracts to U.S. and international companies. HHS also is supporting development of H5N1 vaccines in Vietnam and other countries at risk, and beginning discussions with health officials in Southeast Asia concerning possible joint clinical evaluation of avian influenza vaccines in human subjects. HHS also will continue to support development of pandemic influenza vaccines at eligible international as well as domestic research institutions. HHS, USDA, and the Department of the Interior (DOI) are supporting additional efforts to sequence influenza viruses from wild birds, live bird markets, and pigs in Asia and North America, with plans to expand surveillance and collection sites in the future.

The development of rapid diagnostic tests and the distribution of diagnostic reagents and tests are also critical components of pandemic influenza preparedness. USDA has developed and applied a real-time diagnostic protocol to analyze influenza in animal specimens and is assisting countries to adopt and apply this protocol in support of surveillance and response programs for avian influenza among animals. The HHS Centers for Disease Control and Prevention (CDC) and the private sector have developed high-throughput rapid diagnostic kits that can provide results in 4 hours and will undergo field testing by U.S. and Southeast Asian scientists and public health officials to ascertain the utility and robustness of these products in real-time scenarios for detection and reporting of influenza and other viruses in humans and animals.

### **Effective Public Communication**

Public audiences in affected countries and countries at risk will require targeted communications in local languages to understand the threat of influenza with pandemic potential in animals and of human pandemic influenza, the preventive measures that should be taken now, and what actions must be taken if a pandemic occurs. The WHO Secretariat requires the resources to develop and implement international media and risk communications strategies. The Federal Government is pursuing a two-track approach. HHS, USAID, USDA, DOD, and DOS are implementing coordinated, complementary communication plans to reach their respective constituencies with focused and consistent messages. In addition, the Federal Government is working with the WHO Secretariat to coordinate U.S. Government messages with those of other countries so the public receives the same message from their governments, WHO, and U.S. public health authorities. In addition to executing a comprehensive risk communication strategy in the United States, HHS also is working with health officials overseas to develop effective local language health-based messages for the foreign audiences. USAID and USDA are targeting behavior change communications to poultry farmers and the general public in affected regions and DOS is implementing broad-based domestic and international communications plans that inform U.S. and foreign audiences about international initiatives and plans to address the threat of avian and pandemic influenza.

### **Assistance to United States Citizens Traveling or Living Abroad**

The Federal Government will provide U.S. citizens living and traveling abroad with timely, accurate information on avian influenza, through websites, travel information, and meetings. U.S. Embassies and Consulates in countries in which a virus with pandemic potential has been found in wild and/or domestic birds, or where human cases have occurred, will use town hall meetings and their local warden system information networks to disseminate information and enable U.S. citizens to make informed decisions. U.S. Embassies and Consulates are also working to identify local medical capabilities and resources that would be available to Americans in the event of a “stay in place” response to a pandemic,



noting WHO and HHS advice that the close physical proximity entailed by air travel poses a particular risk of human-to-human transmission. The Federal Government's ability to provide consular assistance to U.S. citizens who are living and traveling abroad in the event of a pandemic may be limited because travel into, out of, or within a country may not be possible, safe, or medically advisable.

### **Assistance to the United States**

We will develop policies to request, accept, and utilize foreign aid, both material and personnel, quickly in the event that a pandemic outbreak first occurs in the United States, or elsewhere in North America or the Western Hemisphere.

## **Roles and Responsibilities**

The responsibility for preparing for, detecting, and responding to an outbreak of influenza with pandemic potential is global. An outbreak anywhere is a threat to populations everywhere. All nations and relevant international organizations have a responsibility to prepare to respond immediately and leverage all resources, domestic and international, to contain human or animal cases, wherever they may occur. In the event of an outbreak, the government of the affected nation has an obligation to report it immediately to appropriate international organizations (e.g., WHO, OIE) and share epidemiological data and samples with relevant international organizations. In addition, the Federal Government, States, tribal entities, and localities, private sector entities with activities overseas, and international health organizations all have key roles to play in fighting pandemic influenza.

### **The Federal Government**

The Federal Government will encourage engagement by other governments, relevant international organizations, and the private sector to strengthen international capacity and commitment to prepare for, detect, and respond to animal or human outbreaks of influenza with pandemic potential.

Department of State: DOS leads the Federal Government's international engagement, bilateral and multilateral, to promote development of global capacity to address an influenza pandemic. With technical support from HHS and USDA, DOS also leads coordination of the Federal Government's international efforts to prepare for and respond to a pandemic, including the interagency process to identify countries requiring U.S. assistance, identify priority activities, and ensure Federal Government assistance reflects those priorities. DOS is also the coordinating agency for the International Coordination Support Annex to the *National Response Plan* (NRP), with assistance provided by other Federal agencies. DOS is responsible for providing consular services to American citizens who are traveling or residing abroad, including endeavoring to inform American citizens abroad where they can obtain up-to-date information and pandemic risk level assessments to enable them to make informed decisions and take appropriate personal protective measures. DOS sets policies for Federal employees who are working abroad under Chief of Mission authority, including in the event of a pandemic.

In carrying out these responsibilities, DOS works closely with other Federal departments and agencies that bring critical expertise to bear and play a key role in our international prevention and containment efforts, including through engagement with their counterparts in foreign governments and with relevant international organizations. Overseas, in particular, Federal Government departments and agencies cooperate under the authority of the Chief of Mission to bring their respective expertise and resources to bear in a coordinated Federal Government effort.

U.S. Agency for International Development: USAID leads on international disaster response, the development of health capacity abroad, including public health capacity, the training of non-health professionals, and operational coordination for the provision of U.S. international health and development assistance. USAID plays a critical role in bridging between the human and animal health sectors to ensure a comprehensive and cross-sectoral international response to the threat of avian influenza. With technical guidance from HHS and USDA respectively, USAID will work closely with WHO and FAO to ensure strong coordination and standardization of efforts to prepare for, identify, and respond to outbreaks of influenza with pandemic potential in either animal or human populations. In addition, working through non-governmental organizations (NGOs) and the private sector, USAID will expand capacities for the early detection of outbreaks, and support behavior change communications and public efforts in affected countries. A key part of these efforts will be to provide direct financial and commodity support to country-level rapid response teams to ensure timely and effective containment of influenza outbreaks in humans and animals.

Department of Health and Human Services: HHS's primary international responsibilities are those actions required to protect the health of all Americans, in cooperation with the Secretariat of the WHO and other technical partners, including leading Federal Government efforts in the surveillance and detection of influenza outbreaks overseas; supporting rapid containment of localized outbreaks of novel human influenza viruses where and when containment is feasible; leading Federal Government participation in international collaboration on research into human influenza, including zoonotic varieties; providing training to foreign health professionals in how to recognize and treat influenza; providing training and guidance to national and local public health authorities in foreign nations on the use, timing, and sequencing of community infection control measures; and implementing any necessary travel restrictions. HHS's international roles and responsibilities are further defined in the International Coordination Support Annex to the NRP. HHS also will work with USAID in developing local-language campaigns overseas to communicate information related to pandemic influenza, and in supporting the U.S. Government's participation in international efforts to stockpile countermeasures against possible influenza pandemics, and offer our international partners recommendations related to the use, distribution, and allocation of such countermeasures. HHS is the lead Federal Government technical agency for interactions within the Global Health Security Action Initiative, manages the development of a North American Pandemic Influenza Plan under the Security and Prosperity Partnership of North America, and supports DOS in diplomatic and scientific efforts undertaken under the umbrella of the International Partnership on Avian and Pandemic Influenza.

Department of Agriculture: USDA leads the Federal Government's participation in international collaboration on animal health research, risk analyses, transboundary movement of animals and animal products, governance of international agricultural organizations (e.g., FAO, OIE), and delivery of veterinary and agricultural expertise to other countries. USDA personnel at U.S. missions throughout the world collect information, facilitate policy dialogue, and encourage host countries' cooperation with the United States and compliance with international standards on matters concerning animal health. USDA conducts agricultural research and technical and policy outreach with its established public (e.g., land-grant universities) and private stakeholders, strategically coordinating with international, domestic, and other Federal Government participants. USDA analyzes the short- and long-term economic impact of influenza outbreaks among animals, as well as the impact of a potential pandemic on the agricultural sector, while pursuing prevention and control strategies to support international agricultural systems and commerce.

Department of Homeland Security: DHS coordinates overall Federal domestic incident management in accordance with the NRP and supports implementation of the International Coordination Support

Annex to the NRP. With respect to the U.S. Government's international efforts to fight pandemic influenza, DHS supports DOS as the coordinating agency for the international component of an incident under the NRP. DHS, in coordination with DOT, will engage the international transportation industry via the various industry associations and groups. DHS, in collaboration with DOS and HHS, leads the effort to engage foreign entities in sharing passenger manifest information on travelers exposed to pandemic influenza. DHS supports DOS, DOT, and HHS efforts with foreign governments to screen and limit travel to the United States of travelers exposed to pandemic influenza.

Department of Transportation: DOT will support DOS efforts to coordinate with other Federal Government participants on international pandemic response. DOT will collaborate with DHS to implement transportation and border measures, conduct outreach with its public and private stakeholders, and provide emergency management and guidance for civil transportation resources and systems. In its role in the global transportation network, DOT will support international efforts by marshaling transportation planning and emergency support activities.

Department of Defense: DOD supports DOS in international engagement to promote global capacity to address an influenza pandemic consistent with its national security mission. DOD is responsible for the protection of its forces, including providing up-to-date information and pandemic risk-level assessments to enable DOD forces abroad to make informed decisions and take appropriate personal protective measures. The first priority of DOD support, in the event of a pandemic, will be to provide sufficient personnel, equipment, facilities, materials, and pharmaceuticals to care for DOD forces, civilian personnel, dependents, and beneficiaries to protect and preserve the operational effectiveness of our forces throughout the globe. DOD sets policies for deployed military forces working abroad in the Geographic Combatant Commander's area of responsibility and under the commander's command authority, consistent with the responsibilities outlined in the Unified Command Plan. DOD, in conjunction with DOS and HHS, will utilize its existing research centers to strengthen recipient nation capability for surveillance, early detection, and rapid response to animal and human avian influenza.

Department of the Treasury: Treasury assists in analyzing potential economic impacts and monitoring and preparing policy responses to pandemic-related international economic developments. Treasury also leads the U.S. Government's engagement with the multilateral development banks (MDB) and international financial institutions (IFI), including encouraging MDB and IFI efforts to assist countries to address the impact of pandemic influenza.

Department of Commerce: DOC facilitates the expedited interagency review for any export licenses needed for items necessary for overseas shipment in response to an avian influenza pandemic. DOC coordinates, as needed, with HHS/CDC to expedite export licenses of strains, test kits/equipment, and technology to specified destinations in order to allow rapid identification of strains, and provide on ground support to contain/mitigate a pandemic to support development of scientific and epidemiological expertise in affected regions to ensure early recognition of changes in pattern of outbreak.

### **State, Local, and Tribal Entities**

State, local, and tribal authorities ensure that foreign diplomatic and consular personnel in the United States are kept informed of developments relevant to their rights and responsibilities under international and domestic law and that they can perform their authorized functions, including functions of consular protection and assistance. In the event of a pandemic, personal inviolability and other privileges and immunities need to be taken into account when protective measures such as quarantine are being consid-

ered, and it will be important that States, localities, and tribal entities afford consular communication and access to non-official foreign nationals who may be quarantined. State, local, and tribal entities, especially those along a U.S. border, should work with DOS on these matters and more generally in pandemic preparedness planning, including engaging with foreign countries and the broader international community on measures to prevent and contain pandemic influenza. The interaction between U.S. States/Tribal Nations and their Canadian and Mexican counterparts, under DOS coordination, will be crucial during implementation of the North American Pandemic Influenza Plan under the Security and Prosperity Partnership.

### **The Private Sector and Critical Infrastructure Entities**

The U.S. Government works with the private sector to leverage its presence and resources overseas to prepare for, detect, and respond to a pandemic.

### **Individuals and Families**

Private Americans who are living or traveling abroad should make personal plans relating to their medical care, ability to address a “stay-in-place” response, and the possibility that international movement will be restricted for public health reasons.

### **International Partners**

Three international organizations play key roles with respect to preparing for, detecting, and containing an outbreak of animal or pandemic influenza. The WHO Secretariat and its Regional Offices and the WHO Influenza Network help build international public health capacity, encourage and assist countries to develop and exercise pandemic preparedness plans, and set international public health standards. The WHO leadership coordinates the international response to an outbreak of pandemic influenza, including through its Global Outbreak Alert and Response Network (GOARN), consistent with the revised International Health Regulations (IHRs) as adopted by the World Health Assembly in May 2005 for entry into force in June 2007, which will govern the obligations of WHO member states to report public health emergencies of international concern to the WHO Secretariat and describe steps countries may take to limit international movement of travelers, conveyances, or cargo to prevent the spread of disease. The OIE and the FAO share the lead on animal health and work with the United States and other nations to detect, respond to, and contain outbreaks of influenza with pandemic potential in animals. The Senior UN System Coordinator for Avian and Human Influenza, appointed by the UN Secretary General in September 2005, will coordinate the efforts of WHO and the full range of UN organizations that may be tapped in the fight against pandemic influenza.

MDBs are preparing to provide loans and technical assistance to help borrowing member countries assess the potential economic impact of and develop action plans to respond to an influenza pandemic. The Asian Development Bank has approved a line of credit and approved grants to fight infectious diseases in Asia, including avian influenza, and has conducted initial economic analysis on the impact that a wider avian influenza outbreak could have on the regional economy. The World Bank has opened a line of credit to fight an influenza pandemic and is establishing a unit to track donor financial commitments and spending.

## Actions and Expectations

### 4.1. Pillar One: Preparedness and Communication

Preparedness is key to an effective effort to contain an outbreak of influenza with pandemic potential at home or abroad. The United States will work to improve the international community's capacity and the commitment to take coordinated, effective action to contain an outbreak at its site of origin if possible and if not, to slow or limit its spread; to provide and coordinate assistance to nations that lack the capacity to detect independently and respond to an outbreak of animal or human influenza with pandemic potential; to develop and exercise pandemic response plans; to increase medical, veterinary, and scientific capacity and national and international supplies of countermeasures; and to communicate clearly and effectively with all stakeholders before and during a pandemic. These international activities will benefit or advance the health of the American people.

#### *a. Planning for a Pandemic*

##### **4.1.1. Support the development and exercising of avian and pandemic response plans.**

- 4.1.1.1. DOS, in coordination with HHS, USAID, DOD, and DOT, shall work with the Partnership, the Senior UN System Coordinator for Avian and Human Influenza, other international organizations (e.g., WHO, World Bank, OIE, FAO) and through bilateral and multilateral initiatives to encourage countries, particularly those at highest risk, to develop and exercise national and regional avian and pandemic response plans within 12 months. Measure of performance: 90 percent of high-risk countries have response plans and plans to test them.
- 4.1.1.2. USDA, USAID, and HHS shall use epidemiological data to expand support for animal disease and pandemic prevention and preparedness efforts, including provision of technical assistance to veterinarians and other agricultural scientists and policymakers, in high-risk countries within 12 months. Measure of performance: all high-risk and affected countries have in place (1) national task forces meeting regularly with representation from both human and animal health sectors, government ministries, businesses, and NGOs; (2) national plans, based on scientifically valid information, developed, tested, and implemented for containing influenza in animals with human pandemic potential and for responding to a human pandemic.
- 4.1.1.3. DOD, in coordination with DOS and other appropriate Federal agencies, host nations and regional alliance military partners, shall, within 18 months: (1) conduct bilateral and multilateral assessments of the avian and pandemic preparedness and response plans of the militaries in partner nations or regional alliances such as NATO focused on preparing for and mitigating the effects of an outbreak on assigned mission accomplishment; (2) develop solutions for identified national and regional military gaps; and (3) develop and execute bilateral and multilateral military-to-military influenza exercises to validate preparedness and response plans. Measure of performance: all countries with endemic avian influenza engaged by U.S. efforts; initial assessment and identification of exercise timeline for the military of each key partner nation completed.



**4.1.2. Expand in-country and abroad, medical, veterinary, and scientific capacity to respond to an outbreak.**

- 4.1.2.1. DOS shall ensure strong U.S. Government engagement in and follow-up on bilateral and multilateral initiatives to build cooperation and capacity to fight pandemic influenza internationally, including the Asia-Pacific Economic Cooperation (APEC) initiatives (inventory of resources and regional expertise to fight pandemic influenza, a region-wide tabletop exercise, a Symposium on Emerging Infectious Diseases to be held in Beijing in April 2006 and the Regional Emerging Disease Intervention (REDI) Center in Singapore), the U.S.-China Joint Initiative on Avian Influenza, and the U.S.-Indonesia-Singapore Joint Avian Influenza Demonstration Project; and shall develop a strategy to expand the number of countries fully cooperating with U.S. and/or international technical agencies in the fight against pandemic influenza, within 6 months. Measure of performance: finalized action plans that outline goals to be achieved and timeframes in which they will be achieved.
- 4.1.2.2. HHS shall staff the REDI Center in Singapore within 3 months. Measure of performance: U.S. Government staff provided to REDI Center.
- 4.1.2.3. USDA, working with USAID and the Partnership, shall support the FAO and OIE to implement an instrument to assess priority countries' veterinary infrastructure for prevention, surveillance, and control of animal influenza and increase veterinary rapid response capacity by supporting national capacities for animal surveillance, diagnostics, training, and containment in at-risk countries, within 9 months. Measure of performance: per the OIE's Performance, Vision and Strategy Instrument, assessment tools exercised and results communicated to the Partnership, and priority countries are developing, or have in place, an infrastructure capable of supporting their national prevention and response plans for avian or other animal influenza.
- 4.1.2.4. USDA, in coordination with DOS, USAID, the OIE, and other members of the Partnership, shall support FAO to enhance the rapid detection and reporting of, response to, and control or eradication of outbreaks of avian influenza, within 12 months. Measure of performance: an international program is established and providing functional support to priority countries with rapid detection and reporting of, response to, and control or eradication of outbreaks of avian influenza, as appropriate to the country's specific situation.
- 4.1.2.5. HHS, in coordination with USAID, shall increase rapid response capacity within those countries at highest risk of human exposure to animal influenza by supporting national and local government capacities for human surveillance, diagnostics, and medical care, and by supporting training and equipping of rapid response and case investigation teams for human outbreaks, within 9 months. Measure of performance: trained, deployable rapid response teams exist in countries with the highest risk of human exposure.
- 4.1.2.6. DOD, in coordination with DOS, host nations, and regional alliance military partners, shall assist in developing priority country military infection control

and case management capability through training programs, within 18 months. Measure of performance: training programs carried out in all priority countries with increased military infection control and case management capability.

- 4.1.2.7. Treasury shall encourage and support MDB programs to improve health surveillance systems, strengthen priority countries' response to outbreaks, and boost health systems' readiness, consistent with legislative voting requirements, within 12 months. Measure of performance: projects that fit relevant MDB criteria approved in at least 50 percent of priority countries.

**4.1.3. Educate people in priority countries about high-risk practices that increase the likelihood of virus transmission from animals and between humans.**

- 4.1.3.1. USAID, HHS, and USDA shall conduct educational programs focused on communications and social marketing campaigns in local languages to increase public awareness of risks of transmission of influenza between animals and humans, within 12 months. Measure of performance: clear and consistent messages tested in affected countries, with information communicated via a variety of media have reached broad audiences, including health care providers, veterinarians, and animal health workers, primary and secondary level educators, villagers in high-risk and affected areas, poultry industry workers, and vendors in open air markets.
- 4.1.3.2. HHS and USAID shall work with the WHO Secretariat and other multilateral organizations, existing bilateral programs and private sector partners to develop community- and hospital-based health prevention, promotion, and education activities in priority countries within 12 months. Measure of performance: 75 percent of priority countries are reached with mass media and community outreach programs that promote AI awareness and behavior change.

***b. Communicating Expectations and Responsibilities***

**4.1.4. Work to ensure clear, effective, and coordinated risk communication, domestically and internationally, before and during a pandemic. This includes identifying credible spokespersons at all levels of government to effectively coordinate and communicate helpful, informative, and consistent messages in a timely manner.**

- 4.1.4.1. DOS and HHS, in coordination with other agencies, shall ensure that the top political leadership of all affected countries understands the need for clear, effective coordinated public information strategies before and during an outbreak of avian or pandemic influenza within 12 months. Measure of performance: 50 percent of priority countries that developed outbreak communication strategies consistent with the WHO September 2004 Report detailing best practices for communicating with the public during an outbreak.
- 4.1.4.2. DOS and HHS, in coordination with other agencies, shall implement programs within 3 months to inform U.S. citizens, including businesses, NGO personnel, DOD personnel, and military family members residing and traveling abroad, where they may obtain accurate, timely information, including risk level assess-

ments, to enable them to make informed decisions and take appropriate personal measures. Measure of performance: majority of registered U.S. citizens abroad have access to accurate and current information on influenza.

- 4.1.4.3. DOS and HHS shall ensure that adequate guidance is provided to Federal, State, tribal, and local authorities regarding the inviolability of diplomatic personnel and facilities and shall work with such authorities to develop methods of obtaining voluntary cooperation from the foreign diplomatic community within the United States consistent with U.S. Government treaty obligations within 6 months. Measure of performance: briefing materials and an action plan in place for engaging with relevant Federal, State, tribal, and local authorities.
- 4.1.4.4. USAID, USDA, and HHS shall work with the WHO Secretariat, FAO, OIE, and other donor countries within 12 months to implement a communications program to support government authorities and private and multilateral organizations in at-risk countries in improving their national communications systems with the goal of promoting behaviors that will minimize human exposure and prevent further spread of influenza in animal populations. Measure of performance: 50 percent of priority countries have improved national avian influenza communications.
- 4.1.4.5. USAID, in coordination with DOS, HHS, and USDA, shall develop and disseminate influenza information to priority countries through international broadcasting channels, including international U.S. Government mechanisms such as Voice of America and Radio Free Asia (radio, television, shortwave, Internet), and share lessons learned and key messages from communications campaigns, within 12 months. Measure of performance: local language briefing materials and training programs developed and distributed via WHO and FAO channels.

***c. Producing and Stockpiling Vaccines, Antiviral Medications, and Medical Material***

**4.1.5. Encourage nations to develop production capacity and stockpiles to support their response needs, to include pooling of efforts to create regional capacity.**

- 4.1.5.1. DOS, in coordination with other agencies, shall use the Partnership and bilateral and multilateral diplomatic contacts on a continuing basis to encourage nations to increase international production capacity and stockpiles of safe and effective human vaccines, antiviral medications, and medical material within 12 months. Measure of performance: increase by 50 percent the number of priority countries that have plans to increase production capacity and/or stockpiles.
- 4.1.5.2. HHS and USAID shall work to coordinate and set up emergency stockpiles of protective equipment and essential commodities other than vaccine and antiviral medications for responding to animal or human outbreaks within 9 months. Measure of performance: essential commodities procured and available for deployment within 24 hours.



- 4.1.5.3. HHS shall provide technical expertise, information, and guidelines for stockpiling and use of pandemic influenza vaccines within 6 months. Measure of performance: all priority countries and partner organizations have received relevant information on influenza vaccines and application strategies.
- 4.1.5.4. USDA and USAID, in cooperation with FAO and OIE, shall provide technical expertise, information and guidelines for stockpiling and use of animal vaccines, especially to avian influenza affected countries and those countries at highest risk, within 6 months. Measure of performance: all priority countries and relevant international organizations have received information on animal vaccines' efficacy and application strategies to guide country-specific decisions about preparedness options

**4.1.6. Facilitate appropriate coordination of efforts across the vaccine manufacturing sector.**

- 4.1.6.1. DOS, in coordination with HHS and other agencies, shall continue to work through the Partnership and other bilateral and multilateral venues to build international cooperation and encourage countries and regional organizations to develop diagnostic, research and vaccine manufacturing capacity within 24 months. Measure of performance: global diagnostic and research capacity increased significantly compared to 24 months earlier; significant investments made to expand international vaccine manufacturing capacity.
- 4.1.6.2. HHS, in coordination with the WHO Secretariat, shall establish at least six new sites for Collaborative Clinical Research on Emerging Infectious Diseases to conduct collaborative clinical research on the diagnostics, therapeutics, and natural history of avian influenza and other human emerging infectious diseases. In addition, within 18 months it will provide in-country support for one or more partner countries for human avian influenza clinical trials. Measure of performance: cooperative programs established in six new sites, to include the initiation of research protocols and design of clinical trials.
- 4.1.6.3. USDA shall generate new information on avian vaccine efficacy and production technologies and disseminate to international organizations, animal vaccine manufacturers, and countries at highest risk within 6 months. Measure of performance: information disseminated to priority entities.

***d. Establishing Distribution Plans for Vaccines and Antiviral Medications***

**4.1.7. Develop credible countermeasure distribution mechanisms for vaccine and antiviral agents prior to and during a pandemic.**

- 4.1.7.1. DOS shall work with HHS and USAID, in collaboration with the WHO Secretariat, to coordinate the U.S. Government contribution to an international stockpile of antiviral medications and other medical countermeasures, including international countermeasure distribution plans and mechanisms and agreed prioritization of allocation, within 6 months. Measure of performance: release of proposed doctrine of deployment and concept of operations for an international stockpile.

- 4.1.7.2. The Department of Justice (DOJ) and DOS, in coordination with HHS, shall consider whether the U.S. Government, in order to benefit from the protections of the Defense Appropriations Act, should seek to negotiate liability-limiting treaties or arrangements covering U.S. contributions to an international stock-pile of vaccine and other medical countermeasures, within 6 months. Measure of performance: review initiated and decision rendered.
- 4.1.7.3. USDA, in collaboration with FAO and OIE, shall develop and provide best-practice guidelines and technical expertise to countries that express interest in obtaining aid in the implementation of a national animal vaccination program, within 4 months. Measure of performance: interested countries receive guidelines and other assistance within 3 months of their request.

***e. Advancing Scientific Knowledge and Accelerating Development***

**4.1.8. Ensure that there is maximal sharing of scientific information about influenza viruses between governments, scientific entities, and the private sector.**

- 4.1.8.1. HHS shall support the Los Alamos H5 Sequence Database and the Institute for Genomic Research (TIGR), for the purpose of sharing avian H5N1 influenza sequences with the scientific community within 24 months. Measure of performance: completed H5 sequences entered into both the Los Alamos database and GenBank and annotated.
- 4.1.8.2. HHS shall enhance a regional influenza genome reference laboratory in Singapore within 9 months. Measure of performance: capacity to sequence complete influenza virus genome established in Singapore; all reported novel animal influenza samples sequenced and made available on public databases.
- 4.1.8.3. USDA and USAID shall work with international organizations, governments, and scientific entities to disseminate and exchange information to bolster and apply avian influenza prevention and response plans in priority countries, within 12 months. Measure of performance: 50 percent of priority countries have national epizootic prevention and response plans based upon pragmatic, comprehensive, and scientifically valid information.
- 4.1.8.4. HHS and DOD, in coordination with DOS, shall enhance open source information sharing efforts with international organizations and agencies to facilitate the characterization of genetic sequences of circulating strains of novel influenza viruses within 12 months. Measure of performance: publication of all reported novel influenza viruses which are sequenced.

**4.2. Pillar Two: Surveillance and Detection**

To increase the probability of containing a virus with pandemic potential that originates outside the United States or delaying its spread as long as possible as we activate protective measures at home, we will need early recognition of the problem. We will work to ensure effective surveillance, rapid detection, and transparent reporting of outbreaks internationally by strengthening scientific and epidemiological expertise abroad; enhancing laboratory capacity and diagnostic

capabilities; and establishing international mechanisms and commitment to ensure transparent and rapid reporting. We will develop, enhance, and encourage early implementation of international screening and monitoring mechanisms to limit the spread of viruses with pandemic potential.

***a. Ensuring Rapid Reporting of Outbreaks***

**4.2.1. Work through the International Partnership on Avian and Pandemic Influenza, as well as through other political and diplomatic channels such as the United Nations and the Asia-Pacific Economic Cooperation forum, to ensure transparency, scientific cooperation, and rapid reporting of avian and human influenza cases.**

- 4.2.1.1. DOS, in coordination with other agencies, shall work on a continuing basis through the Partnership and through bilateral and multilateral diplomatic contacts to promote transparency, scientific cooperation, and rapid reporting of avian and human influenza cases by other nations within 12 months. Measure of performance: all high-risk countries actively cooperating in improving capacity for transparent, rapid reporting of outbreaks.
- 4.2.1.2. HHS, in coordination with DOS, shall pursue bilateral agreements with key affected countries on health cooperation including transparency, sample and data sharing, and development of rapid response protocols; and develop and train in-country rapid response teams to quickly assess and report on possible outbreaks of avian and human influenza, within 12 months. Measure of performance: agreements established with Vietnam, Cambodia, and Laos, 100 teams throughout Asia, including China, Thailand, and Indonesia, trained and available to respond to outbreaks.
- 4.2.1.3. HHS shall place long-term staff at key WHO offices and in select affected and high-risk countries to provide coordination of HHS-sponsored activities and to serve as liaisons with HHS within 9 months. Measure of performance: placement of staff and increased coordination with the WHO Secretariat and Regional Offices.
- 4.2.1.4. HHS shall, to the extent feasible, negotiate agreements with established networks of laboratories around the world to enhance its ability to perform laboratory analysis of human and animal virus isolates and to train in-country government staff on influenza-related surveillance and laboratory diagnostics, within 6 months. Measure of performance: completed, negotiated agreement, and financing mechanism with at least one laboratory network outside the United States.
- 4.2.1.5. HHS shall support the WHO Secretariat to enhance the early detection, identification and reporting of infectious disease outbreaks through the WHO's Influenza Network and Global Outbreak and Alert Response Network (GOARN) within 12 months. Measure of performance: expansion of the network to regions not currently part of the network.

- 4.2.1.6. USAID, in coordination with USDA, shall initiate a pilot program to evaluate strategies for farmer compensation and shall engage and leverage the private sector and other donors to increase the availability of key commodities, compensation, financing and technical support for the control of avian influenza, within 6 months. Measure of performance: a model compensation program measured in value of goods and services available for compensation is developed.
- 4.2.1.7. USAID, HHS, USDA, and DOS shall support NGOs, FAO, OIE, WHO, the Office of the Senior UN System Coordinator for Avian and Human Influenza, and host governments to expand the scope, accuracy, and transparency of human and animal surveillance systems and to streamline and strengthen official protocols for reporting avian influenza cases, within 6 months. Measure of performance: 75 percent of priority countries have established early warning networks, international case definitions, and standards for laboratory diagnostics of human and animal samples.

**4.2.2. Support the development of the proper scientific and epidemiologic expertise in affected regions to ensure early recognition of changes in the pattern of avian or human outbreaks.**

- 4.2.2.1. HHS and USDA, in collaboration with one or more established networks of laboratories around the world, including the WHO Influenza Network, shall train staff from priority countries' Ministries of Health and Agriculture, to conduct surveillance and perform epidemiologic analyses on influenza-susceptible species and manage and report results of findings, within 12 months. Measure of performance: 75 percent of priority countries have access to multi-year epidemiology and surveillance training programs.
- 4.2.2.2. HHS and USDA shall increase support of scientists tracking potential emergent influenza strains through disease and virologic surveillance in susceptible animal species in priority countries within 9 months. Measure of performance: surveillance for emergent influenza strains expanded in priority countries.
- 4.2.2.3. HHS, in coordination with DOD, shall provide support to Naval Medical Research Unit (NAMRU) 2 in Jakarta, Indonesia and Phnom Penh, Cambodia, the Armed Forces Research Institute of Medical Sciences in Bangkok, Thailand, and NAMRU-3 in Cairo, Egypt to expand and expedite geographic surveillance of human populations at-risk for H5N1 infections in those and neighboring countries through training, enhanced surveillance, and enhancement of the Early Warning Outbreak Recognition System, within 12 months. Measure of performance: reagents and technical assistance provided to countries in the network to improve and expand surveillance of H5N1 and number of specimens tested by real-time processing.
- 4.2.2.4. HHS shall enhance surveillance and response to high priority infectious disease, including influenza with pandemic potential, by training physicians and public health workers in disease surveillance, applied epidemiology and outbreak response at its GDD Response Centers in Thailand and China and at the U.S.-China Collaborative Program on Emerging and Re-Emerging Infectious

Diseases, within 12 months. Measure of performance: 50 physicians and public health workers living in priority countries receive training in disease surveillance applied epidemiology and outbreak response.

4.2.2.5. DOD shall develop active and passive systems for inpatient and outpatient disease surveillance at its institutions worldwide, with an emphasis on index case and cluster identification, and develop mechanisms for utilizing DOD epidemiological investigation experts in international support efforts, to include validation of systems/tools and improved outpatient/inpatient surveillance capabilities, within 18 months. Measure of performance: monitoring system and program to utilize epidemiological investigation experts internationally are in place.

4.2.2.6. DOD shall monitor the health of military forces worldwide (CONUS and OCONUS bases, deployed operational forces, exercises, units, etc.), and in coordination with DOS, coordinate with allied, coalition, and host nation public health communities to investigate and respond to confirmed infectious disease outbreaks on DOD installations, within 18 months. Measure of performance: medical surveillance “watchboard” reports show results of routine monitoring, number of validated outbreaks, and results of interventions.

4.2.2.7. DOD, in coordination with DOS and with the cooperation of the host nation, shall assist with influenza surveillance of host nation populations in accordance with existing treaties and international agreements, within 24 months. Measure of performance: medical surveillance “watchboard” expanded to include host nations.

**4.2.3. Support the development and sustainment of sufficient U.S. and host nation laboratory capacity and diagnostic reagents in affected regions and domestically, to provide rapid confirmation of cases in animals or humans.**

4.2.3.1. HHS shall develop and implement laboratory diagnostics training programs in basic laboratory techniques related to influenza sample preparation and diagnostics in priority countries within 9 months. Measure of performance: 25 laboratory scientists trained in influenza sample preparation and diagnostics.

4.2.3.2. HHS in collaboration with one or more established networks of laboratories, including the WHO Influenza Network, shall train staff from priority countries on influenza-related laboratory diagnostics, within 12 months. Measure of performance: 100 percent of priority countries have training programs established.

4.2.3.3. HHS, in cooperation with the WHO Secretariat and other donor countries, shall expand an existing specimen transport fund that enables developing countries to transport influenza samples to WHO regional reference laboratories and collaborating centers, within 6 months. Measure of performance: 100 percent of priority countries funded for sending influenza samples to WHO regional reference laboratories.

- 4.2.3.4. HHS shall invest in the development and evaluation of more accurate rapid diagnostics for influenza to enhance the ability of the global healthcare community to rapidly diagnose influenza, within 18 months. Measure of performance: new grants and contracts issued to researchers to develop and evaluate new diagnostics.
- 4.2.3.5. HHS and USAID shall work with the WHO Secretariat and private sector partners, through existing bilateral agreements, to provide support for human health diagnostic laboratories by developing and giving assistance in implementing rapid international laboratory diagnostics protocols and standards in priority countries, within 12 months. Measure of performance: 75 percent of priority countries have improved human diagnostic laboratory capacity.
- 4.2.3.6. USDA and USAID shall work with FAO and OIE to provide technical support for animal health diagnostic laboratories by developing and implementing international laboratory diagnostic protocols, standards, and infrastructure in priority countries that can rapidly screen avian influenza specimens from susceptible animal populations, within 12 months. Measure of performance: 75 percent of priority countries have improved animal diagnostic laboratory capacity.
- 4.2.3.7. USDA and USAID shall provide technical expertise to help priority countries develop their cadre of veterinary diagnostic technicians to screen avian influenza specimens from wild and domestic bird populations, and other susceptible animals, rapidly and in a manner that adheres to international standards for proficiency and safety, within 12 months. Measure of performance: all priority countries have access to laboratories that are able to screen avian influenza specimens and confirm diagnoses in a manner that supports effective control of cases of avian influenza.
- 4.2.3.8. DOD, in coordination with HHS, shall develop and refine its overseas virologic and bacteriologic surveillance infrastructure through Global Emerging Infections Surveillance and Response System (GEIS) and the DOD network of overseas labs, including fully developing and implementing seasonal influenza laboratory surveillance and an animal/vector surveillance plan linked with WHO pandemic phases, within 18 months. Measure of performance: animal/vector surveillance plan and DOD overseas virologic surveillance network developed and functional.
- 4.2.3.9. DOD, in coordination with HHS, shall prioritize international DOD laboratory research efforts to develop, refine, and validate diagnostic methods to rapidly identify pathogens, within 18 months. Measure of performance: completion of prioritized research plan, resources identified, and tasks assigned across DOD medical research facilities.
- 4.2.3.10. DOD shall work with priority nations' military forces to assess existing laboratory capacity, rapid response teams, and portable field assay testing equipment, and fund essential commodities and training necessary to achieve an effective national military diagnostic capability, within 18 months. Measure of perform-



ance: assessments completed, proposals accepted, and funding made available to priority countries.

***b. Using Surveillance to Limit Spread***

**4.2.4. Develop mechanisms to rapidly share information on travelers who may be carrying or may have been exposed to a pandemic strain of influenza, for the purposes of contact tracing and outbreak investigation.**

4.2.4.1. HHS and USAID shall, in coordination with regional and international multi-lateral organizations, develop village-based alert and response surveillance systems for human cases of influenza in priority countries, within 18 months. Measure of performance: 75 percent of all priority countries have established a village alert and response system for human influenza.

4.2.4.2. DOD shall incorporate international public health reporting requirements for exposed or ill military international travelers into the Geographic Combatant Commanders' pandemic influenza plans within 18 months. Measure of performance: reporting requirements incorporated into Geographic Combatant Commanders' pandemic influenza plans.

**4.2.5. Develop and exercise mechanisms to provide active and passive surveillance during an outbreak, both within and beyond our borders.**

4.2.5.1. HHS and USAID shall develop, in coordination with the WHO Secretariat and other donor countries, rapid response protocols for use in responding quickly to credible reports of human-to-human transmission that may indicate the beginnings of an influenza pandemic, within 12 months. Measure of performance: adoption of protocols by WHO and other stakeholders.

4.2.5.2. HHS, in coordination with DOS and other agencies participating in the Security and Prosperity Partnership, shall pursue cooperative agreements on pandemic influenza with Canada and Mexico to create and implement a North American early warning surveillance and response system in order to prevent the spread of infectious disease across the borders, within 9 months. Measure of performance: implementation of early warning surveillance and response system.

4.2.5.3. USDA and USAID shall provide technical expertise to priority countries in order to expand the scope and accuracy of systematic surveillance of avian influenza cases, within 12 months. Measure of performance: 75 percent of priority countries have expanded animal surveillance capabilities.

**4.2.6. Expand and enhance mechanisms for screening and monitoring animals that may harbor viruses with pandemic potential.**

4.2.6.1. DHS, USDA, DOI, and USAID, in collaboration with priority countries, NGOs, WHO, FAO, OIE, and the private sector shall support priority country animal health activities, including development of regulations and enforcement capacities that conform to OIE standards for transboundary movement of animals,

development of effective biosecurity measures for commercial and domestic animal operations and markets, and identification and confirmation of infected animals, within 12 months. Measure of performance: 50 percent of priority countries have implemented animal health activities as defined above.

**4.2.7. Develop screening and monitoring mechanisms and agreements to appropriately control the movement and shipping of potentially contaminated products to and from affected regions if necessary, and to protect unaffected populations.**

4.2.7.1. DOS, in coordination with DOT, DHS, HHS, and U.S. Trade Representative (USTR), shall collaborate with WHO, the International Civil Aviation Organization (ICAO), and the International Maritime Organization (IMO) to assess and revise, as necessary and feasible, existing international agreements and regulations governing the movement and shipping of potentially infectious products, in order to ensure that international agreements are both adequate and legally sufficient to prevent the spread of infectious disease, within 12 months. Measure of performance: international regulations reviewed and revised.

4.2.7.2. USDA shall provide technical assistance to priority countries to increase safety of animal products by identifying potentially contaminated animal products, developing screening protocols, regulations, and enforcement capacities that conform to OIE avian influenza standards for transboundary movement of animal products, within 36 months. Measure of performance: all priority countries have protocols and regulations in place or in process.

**4.2.8. Share guidance with international partners on best practices to prevent the spread of influenza, including within hospitals and clinical settings.**

4.2.8.1. HHS and USAID shall develop community- and hospital-based infection control and prevention, health promotion, and education activities in local languages in priority countries within 9 months. Measure of performance: local language health promotion campaigns and improved hospital-based infection control activities established in all Southeast Asian priority countries.

**4.3. Pillar Three: Response and Containment**

The United States is working now with other nations and relevant international organizations to detect and contain outbreaks of animal influenza with pandemic potential with the aim of preventing its spread to humans. We will work to ensure nations and relevant international organizations agree as soon as possible on a doctrine of international response and containment to implement in the event of a human outbreak. Once health authorities signal sustained, efficient human transmission of a virus with pandemic potential overseas, we will encourage rigorous implementation of the agreed doctrine for international containment and response and offer technical expertise and assistance as needed. Critical to this effort will be the timely implementation of a coordinated and accurate international public awareness campaign to define the facts and establish realistic expectations. We will monitor economic and social effects of a pandemic and employ appropriate measures to limit their impact on global stability and security.



**a. Containing Outbreaks****4.3.1. Work to develop a coalition of strong partners to coordinate actions to limit the spread of a virus with pandemic potential beyond the location where it is first recognized abroad in order to protect U.S. interests.**

- 4.3.1.1. DOS, in coordination with HHS, USDA, USAID, and DOD, shall coordinate the development and implementation of U.S. capability to respond rapidly to assess and contain outbreaks of avian influenza with pandemic potential abroad, including coordination of the development, training and exercise of U.S. rapid response teams; and coordination of U.S. support for development, training and exercise of, and U.S. participation in, international support teams. Measure of performance: agreed operating procedures and operational support for U.S. rapid response, and for U.S. participation in international rapid response efforts, are developed and function effectively.
- 4.3.1.2. DOS, in coordination with HHS, shall work with WHO and the international community to secure agreement (e.g., through a resolution at the World Health Assembly in May 2006) on an international containment strategy to be activated in the event of a human outbreak, including an accepted definition of a “triggering event” and an agreed doctrine for coordinated international action, responsibilities of nations, and steps they will take, within 4 months. Measure of performance: international agreement on a response and containment strategy.
- 4.3.1.3. HHS, in coordination with DOS, and the WHO Secretariat, and USDA, USAID, DOD, as appropriate, shall rapidly deploy disease surveillance and control teams to investigate possible human outbreaks through WHO’s GOARN network, as required. Measure of performance: teams deployed to suspected outbreaks within 48 hours of investigation request.
- 4.3.1.4. DOS, in coordination with HHS, and the WHO Secretariat, and USDA, USAID, DOD, as appropriate, shall coordinate United States participation in the implementation of the international response and containment strategy (e.g., assigning experts to the WHO outbreak teams and providing assistance and advice to ministries of health on local public health interventions, ongoing disease surveillance, and use of antiviral medications and vaccines if they are available). Measure of performance: teams deployed to suspected outbreaks within 48 hours of investigation request.
- 4.3.1.5. USDA and USAID, in coordination with DOS, HHS, and DOD, and in collaboration with relevant international organizations, shall support operational deployment of rapid response teams and provide technical expertise and technology to support avian influenza assessment and response teams in priority countries as required. Measure of performance: all priority countries have rapid access to avian influenza assessment and response teams; deployment assistance provided in each instance and documented in a log of technical assistance rendered.

- 
- 4.3.1.6. DOS shall lead U.S. Government engagement with the international community's effort to develop a coordinated plan for avian influenza assistance (funds, materiel, and personnel) to streamline national assistance efforts within 12 months. Measure of performance: commitments from countries on funds, personnel, and materiel they will contribute to an integrated and prioritized international prevention, preparedness, and response effort.
- 4.3.1.7. DOS, in coordination with and drawing on the expertise of USAID, HHS, and DOD, shall work with the international community to develop, within 12 months, a coordinated, integrated, and prioritized distribution plan for pandemic influenza assistance that details a strategy for (1) strategic lift of WHO stockpiles and response teams; (2) theater distribution to high-risk countries; (3) in-country coordination to key distribution areas; and (4) establishment of internal mechanisms within each country for distribution to urban, rural, and remote populations. Measure of performance: commitments by countries that specify their ability to support distribution, and specify the personnel and material for such support.
- 4.3.1.8. DOS, in coordination with HHS, USDA, USAID, and DHS, and in collaboration with WHO, FAO, OIE, the World Bank and regional institutions such as APEC, the Association of Southeast Asian Nations and the European Community, shall work to improve public affairs coordination and establish a set of agreed upon operating principles among these international organizations and the United States that describe the actions and expectations of the public affairs strategies of these entities that would be implemented in the event of a pandemic, within 6 months. Measure of performance: list of key public affairs contacts developed, planning documents shared, and coordinated public affairs strategy developed.
- 4.3.1.9. DOS and DOC, in collaboration with NGOs and private sector groups representing business with activities abroad, shall develop and disseminate checklists of key activities to prepare for and respond to a pandemic, within 6 months. Measure of performance: checklists developed and disseminated.
- 4.3.2. Where appropriate, use governmental authorities to limit movement of people, goods, and services into and out of areas where an outbreak occurs.**
- 4.3.2.1. DOS, in coordination with DHS, HHS, DOD, and DOT, and in collaboration with foreign counterparts, shall support the implementation of pre-existing passenger screening protocols in the event of an outbreak of pandemic influenza. Measure of performance: protocols implemented within 48 hours of notification of an outbreak of pandemic influenza.
- 4.3.2.2. DOD, in coordination with DOS, HHS, DOT, and DHS, shall limit official DOD military travel between affected areas and the United States. Measure of performance: DOD identifies military facilities in the United States and OCONUS that will serve as the points of entry for all official travelers from affected areas, within 6 months.
-

***b. Leveraging International Medical and Health Surge Capacity*****4.3.3. Activate plans to distribute medical countermeasures, including non-medical equipment and other material, internationally.**

4.3.3.1. DOS, in coordination with HHS, USAID, USDA, and DOD, shall work with the Partnership to assist in the prompt and effective delivery of countermeasures to affected countries consistent with U.S. law and regulation and the agreed upon doctrine for international action to respond to and contain an outbreak of influenza with pandemic potential. Measure of performance: necessary countermeasures delivered to an affected area within 48 hours of agreement to meet request.

**4.3.4. Address barriers to the flow of public health, medical, and veterinary personnel across international borders to meet local shortfalls in public health, medical, and veterinary capacity.**

4.3.4.1. DOS in collaboration with the Partnership and WHO shall negotiate international instruments and/or arrangements to facilitate the flow of rapid response teams and other public health, medical, and veterinary personnel across international borders, within 12 months. Measure of performance: negotiated agreements for facilitating deployment of rapid response teams deployed across international borders using instruments and/or arrangements as detailed above, within 48 hours of request.

4.3.4.2. DHS shall assist in the expeditious movement of public health, medical, and veterinary officials, equipment, supplies, and biological samples for testing through U.S. ports of entry/departure. Measure of performance: delivery of persons, equipment, and samples involved in the detection of and response to outbreaks of avian or pandemic influenza within 48 hours of decision to deploy.

***c. Sustaining Infrastructure, Essential Services, and the Economy*****4.3.5. Analyze the potential economic and social impact of a pandemic on the stability and security of the international community and identify means to address it.**

4.3.5.1. DOS shall organize an interagency group to analyze the potential economic and social impact of a pandemic on the stability and security of the international community, within 3 months. Measure of performance: issues identified and policy recommendations prepared.

4.3.5.2. Treasury shall urge the IMF to enhance its surveillance of priority countries and regions, including further assessment of the macroeconomic and financial vulnerability to an influenza pandemic, within 3 months. Measure of performance: updated, expanded IMF analysis of the potential impact of an influenza pandemic on priority countries and regions, as defined above.

4.3.5.3. Treasury, in collaboration with the IMF and the multilateral development banks, shall take the lead on dialogue with creditor countries to ensure that financial assistance to affected economies is provided on terms consistent with the goals

of restoring economic activity and maximizing economic growth (within existing international financial agreements), within 6 months. Measure of performance: official financing strategies in place that are consistent with the goals above.

***d. Ensuring Effective Risk Communication***

**4.3.6. Ensure that timely, clear, coordinated messages are delivered to the American public from trained spokespersons at all levels of government and assist the governments of affected nations to do the same.**

- 4.3.6.1. DOS, in coordination with HHS, USAID, USDA, DOD, and DHS, shall lead an interagency public diplomacy group to develop a coordinated, integrated, and prioritized plan to communicate U.S. foreign policy objectives relating to our international engagement on avian and pandemic influenza to key stakeholders (e.g., the American people, the foreign public, NGOs, international businesses), within 3 months. Measure of performance: number and range of target audiences reached with core public affairs and public diplomacy messages, and impact of these messages on public responses to avian and pandemic influenza.
- 4.3.6.2. DOS, in coordination with HHS, shall provide at least monthly updates to its foreign counterparts, through diplomatic channels and U.S. Government websites, regarding changes to national policy or regulations that may result from an outbreak, and shall coordinate posting of such information to U.S. Government websites (e.g., [www.pandemicflu.gov](http://www.pandemicflu.gov)). Measure of performance: foreign governments and key stakeholders receive authoritative and regular information on U.S. Government avian influenza policy.
- 4.3.6.3. USDA, in coordination with DHS, USTR, and DOS, shall ensure that clear and coordinated messages are provided to international trading partners regarding animal disease outbreak response activities in the United States. Measure of performance: within 24 hours of an outbreak, appropriate messages will be shared with key animal/animal product trading partners.

## CHAPTER 5 — TRANSPORTATION AND BORDERS

### Introduction

Our Nation's 317 official ports of entry and vast transportation network are critical elements in our preparation for and response to a potential influenza pandemic. Our border measures might provide an opportunity to slow the spread of a pandemic to the United States, but are unlikely to prevent it. The sheer volume of traffic and the difficulty of developing screening protocols to detect an influenza-like illness pose significant challenges. On a typical day, about 1.1 million passengers and pedestrians cross our borders, as do approximately 64,000 truck, rail, and sea containers, 2,600 aircraft, and 365,000 vehicles.

Our transportation system regularly delivers essential commodities to communities, and — in emergencies — rapidly moves critical supplies, emergency workers, and needed resources into affected areas. This vast and complex system moves billions of people and trillions of dollars worth of goods each year. Each of the six major transportation modes (i.e., aviation, rail, highway, maritime, pipeline, and mass transit) has unique characteristics, operating models, responsibilities, and stakeholders. As a decentralized network, the transportation sector is predominantly owned and operated by State and local governments and the private sector. Decisions made by State and local entities and the private sector can have cascading impacts across the transportation sector. Effective transportation management during a pandemic will require planning and close coordination across the sector — at the national, State, and local levels — and with those who depend on it.

Our ability to help maintain infrastructure services, mitigate adverse economic impacts, and sustain societal needs will hinge in part on our ability to make effective international and domestic transportation decisions. While the overall pandemic response will be driven by disease characteristics and the status of domestic preparation, transportation and border decisions should also be based on the effectiveness of an action in slowing the spread of a pandemic and related health benefits; its social and economic consequences; its international implications; and its operational feasibility.

### Key Considerations

#### Goals of Transportation and Border Measures

The *National Strategy for Pandemic Influenza (Strategy)* guides our preparedness and response to an influenza pandemic, with the intent of (1) stopping, slowing, or otherwise limiting the spread of a pandemic to the United States, (2) limiting the domestic spread of a pandemic and mitigating disease, suffering, and death, and (3) sustaining infrastructure and mitigating impact to the economy and the functioning of society. Transportation and border measures, when combined with other social distancing and public health measures, can help support these goals.

The containment of an influenza virus with pandemic potential at its origin — whether the outbreak occurs abroad or within the United States — is a critical element of pandemic response efforts. Containment is most effective when approached globally, with all countries striving to achieve common goals. Even if such efforts prove unsuccessful, delaying the spread of disease could provide the Federal Government with valuable time to activate the domestic response. The Secretariat of the World Health

Organization (WHO) has established guidelines to support the control of spread of a pandemic virus across and within borders.<sup>3</sup> These guidelines provide a useful starting point for the development of U.S. Government national policy and could be modified and extended where necessary. The specifics of how a novel influenza virus will enter the United States and how the epidemic will actually unfold are unknown, and therefore, implementation of U.S. Government response must remain flexible and adaptable to a pandemic as it unfolds. To the extent possible and in accordance with treaties or other binding agreements, the United States will seek to coordinate containment measures with global organizations and partners.

Building on the International Efforts set forth in Chapter 4, this chapter identifies actions to address a number of key policy issues, including developing a cohesive, integrated U.S. border entry and exit strategy for aviation, maritime, and land border ports of entry, and a strategy to guide domestic efforts to delay the spread of disease. Within this policy framework, the Federal Government will develop a toolkit of options that can be used by individuals, within communities and States, and across the Nation. This toolkit will require significant, collaborative planning with States, communities, and the private sector to develop a range of scalable options, the protocols to implement them, and the trigger points that define thresholds to implement and remove measures. It will be critical to quantify, to the extent possible, the costs and benefits of these options, as many of the options will have significant second- and third-order effects.

Deciding which measures to use at which points in the lifecycle of a pandemic will require complex decisions that carefully weigh costs and benefits to evaluate which options best serve the public. Key factors that affect decision making include the ability to delay the pandemic and the resulting health benefits, the associated social and economic consequences, and the operational feasibility to implement transportation or border measures.

#### *Ability to Delay a Pandemic and Resulting Health Benefits*

There are many public health interventions and social distancing measures that can help limit international spread, reduce spread within nations and local populations, and reduce an individual's risk for infection.<sup>4</sup> Transportation and border measures are two of many social distancing measures that can reduce transmission by limiting the proximity of individuals and reducing interaction within and across social networks. Modeling indicates that these measures are most effective when used in combination with other social distancing and public health measures, such as school closures, canceling large public gatherings, and limiting work group interaction.

Research is underway to better understand the effects of movement restrictions and their interactions with other social distancing measures in delaying a pandemic. Current models suggest that highly restrictive border measures could delay a pandemic by a few weeks. However, given the economic and societal impacts of these measures, recent recommendations from WHO encourage countries to focus their efforts to contain spread of a pandemic at national and community levels rather than at international borders. Based on a review of prior pandemics, including quarantines enacted during the 1918 pandemic as well as the 2003 SARS and influenza outbreak, WHO recommendations for border-related measures focus on providing information to international travelers, screening travelers departing countries with transmissible human infection, and limiting travel to affected areas. The

---

<sup>3</sup>World Health Organization. WHO global influenza preparedness plan: the role of WHO and recommendations for national measures before and during pandemics. November 2005.

---

<sup>4</sup>World Health Organization. Non-pharmaceutical interventions for pandemic influenza, international measures. 2006. Emerging Infection Diseases, Vol. 12, No. 1, Jan 2006.



recommendations for national and community measures during a pandemic focus on delaying spread and reducing effects through population-based measures.<sup>5</sup> If the pandemic becomes severe, WHO recommends countries encourage social distancing measures and defer non-essential domestic travel to affected areas. As part of our pandemic planning efforts, guidance and protocols for border and domestic transportation measures will be developed that can be tailored, in the event of a pandemic, based on our level of domestic preparedness and real-time epidemiological disease characteristics, including transmission pattern, pandemic stage, and illness severity and extent.

Depending on the length, delay can provide valuable time to implement pandemic preparedness measures that have been planned in advance.<sup>6</sup> A delay in spread may also allow the administration of pre-pandemic vaccine, assessment of disease epidemiology, and mobilization of resources for screening and diagnosis. It should be noted that current estimates are that it will take approximately 5 months to develop, produce, and distribute a pandemic vaccine after the declaration of a pandemic and isolation of the pandemic virus. While delay may reduce peak overall demand on the health care system, this will not necessarily translate to benefits at the community level. It is unlikely that communities will be able to shift scarce resources that will be needed locally once the pandemic reaches their area. Unlike a hurricane or other localized disaster, national capacity will not be easily distributed across communities and States. Scarce resources, such as personnel and ventilators, will be needed to meet local demand, and it is unlikely that transporting large numbers of infected patients out of medically overwhelmed areas would be a viable option (see Chapter 6 - Protecting Human Health).

Further work will be done to better understand the potential delay that can be obtained through transportation and border measures, how these measures work in concert with other public health and social distancing measures, and the resulting health benefits.

### *Social and Economic Consequences*

The transportation system and the choices it offers support the social, economic, and business needs of communities. Travel is a critical part of our daily routine, with Americans taking an average of 1.1 billion trips per day, or about four trips for every person in the United States each day.<sup>7</sup> A pandemic will require curtailment in travel and dramatically change our travel priorities, choices, and decisions, resulting in significant social and economic consequences.

By carefully examining the public's reliance on travel, existing travel patterns, and anticipated changes in travel during a pandemic, communities and States can develop a range of travel options that help delay spread of the pandemic, but also minimize social and economic consequences. For example, travel options can range from provision of travel information, voluntary advisories with health warnings, selective restrictions that limit certain types of travel, advance notification followed by a defined period of restriction, and mandatory measures under extreme circumstances.

At the onset of a pandemic, the public will almost certainly automatically limit vacation travel, and this would be recommended by public health authorities. It is anticipated that significant portions of business travel would be curtailed as well, with only essential travel continuing (related to overall pandemic response, sustaining critical infrastructure, and sustaining essential business functions). The purpose of

<sup>5</sup>World Health Organization. Non-pharmaceutical interventions for pandemic influenza, national and community measures. 2006. Emerging Infection Diseases, Vol. 12, No. 1, Jan 2006.

<sup>7</sup>U.S. Department of Transportation, Bureau of Transportation Statistics, Federal Highway Administration, National Household Travel Survey data, CD-ROM, February 2004.

<sup>6</sup>World Health Organization. WHO global influenza preparedness plan: the role of WHO and recommendations for national measures before and during pandemics. November 2005.

long-distance travel will also change. Initially, there may be a small surge in trips as people who are out of town return home. During an evolving pandemic it would not be surprising to expect family members to attempt to return home, as well as travel to assist other family members in need, such as elderly parents, ill family members, or others requiring special assistance.

In addition, it is presumed that the public will change daily travel patterns based on what they perceive will reduce their personal risk and the risk to their families and friends. Communities might see a surge in local travel as people gather groceries and other items similar to patterns before large snow storms where the public expects limitations in local travel for short durations. The planned length of travel curtailment is a significant factor that will help families and communities prepare for potential restrictions.

Clear messages regarding travel, risk of transmission, and specific travel recommendations for each stage of a pandemic will be important during a pandemic, and even more critical to guide preparedness efforts. There is a wide range of options that can be used to reduce overall travel, such as provision of travel information, voluntary advisories with health warnings, selective restrictions that limit certain types of travel, advance notification followed by a defined period of restriction, and mandatory measures that would prohibit all travel under extreme circumstances.

As travel restriction policies are evaluated, it will be critical to include the societal consequences of restrictions on individuals, families, and communities. Economic consequences vary widely based on transportation and border actions, but are discussed more under the following section.

Significant planning will be needed at local, State, and national levels to increase the Nation's preparedness, including joint planning to identify the range of transportation options and the supporting policies to facilitate safe transportation of food, fuel, and other critical supplies to affected communities, to help delay the spread with minimal societal and economic consequences.

#### *Operational Feasibility*

Effective transportation and border decisions must also consider operational feasibility, which includes evaluating how travel or trade measures could affect all relevant aspects of the transportation system and carefully weighing competing interests, views, and goals. Such an approach considers the complex, interconnected relationships of a decentralized network where small changes can strategically change travel and trade patterns or unknowingly transfer risk and/or create a secondary layer of challenges. For example, closure of a community to reduce spread would also sever that community from "just-in-time" deliveries to restock grocery stores, pharmacies, and could impede incoming emergency teams and or supplies for the medical and emergency response efforts underway. Even strong messages to reduce non-essential travel voluntarily, if not fully explained and accompanied by clear guidelines of how transport workers can reduce personal risk, could significantly reduce the movement of essential goods and availability of emergency transportation services. Transportation providers will be concerned about protecting their employees, risks to travelers and goods, and the potential impact on facilities and vehicles.

An operational approach gives full consideration to linkages, tradeoffs, or impacts on other transportation entities, facilities, systems, or users. Moreover, this approach considers non-health issues, such as manpower, market factors, how the transportation system operates, and the potential to transfer risk across the network. For example, mandatory restrictions in air travel could potentially transfer travel to other modes, such as rail or personal vehicles. The redundancies of the transportation network can make restrictions challenging to implement. However, a robust planning effort with the public, communities, and transportation providers and stakeholders can develop options based on a joint



understanding of risk, the natural changes in travel patterns, advance notice to aid preparedness, and, in extreme circumstances, mandatory restrictions to safeguard communities.

Curtailment and changes in border and transportation operations will be essential during a pandemic response and to a certain extent will likely occur spontaneously. Transportation professionals and planners will be a valuable resource to assist with the pre-pandemic planning that anticipates these changes and help communities and public health professionals identify how to achieve public health goals related to travel and trade at the time of a pandemic. This demands inclusive decision making with all parties involved both during pre-pandemic planning and at the earliest stages of the process, when issues and potential problems are first defined.

### **Circumstances and Impacts of Complete Border Closure**

Any nation, including the United States, has the sovereign right to control, and if necessary, close its borders. However, in the event of a pandemic, a border closure would likely delay but not stop the spread of influenza to the United States, and would have significant negative social, economic, and foreign policy consequences. Other less drastic measures could potentially be layered to provide similar benefits without the substantial negative consequences of a complete border closure. The discussion below addresses U.S. border closure, as well as the potential that foreign countries may close their borders in response to a pandemic influenza outbreak in the United States.

In the absence of any border or travel restrictions, cases of pandemic influenza would likely arrive in the United States within 1 to 2 months after the virus first emergence elsewhere in the world. Current models suggest that highly restrictive border measures might delay the peak of pandemic by a few weeks. Depending on the length of delay, national preparedness may be enhanced as previously described.

An outbreak of pandemic influenza abroad might result in other countries closing their borders and generate calls for similar action in the United States. Outbreaks in Canada or Mexico might further increase pressure to close U.S. borders. Conversely, an outbreak within the United States might result in other countries closing their borders to the United States to delay spread. This could have a significant impact on overseas commerce, military missions, and the movement of American citizens.

A United States border closure would have a devastating economic impact, interrupt delivery of essential services, and would disrupt substantial cross-border commerce, resulting in hardship at manufacturing and production plants that rely on export markets and just-in-time delivery. United States international trade was almost \$2.3 trillion in 2004,<sup>8</sup> with \$599 billion in international air freight alone.<sup>9</sup> Given the importance of maritime trade to the U.S. economy,<sup>10</sup> any significant disruptions to trade at our seaports will have immediate and significant economic impacts. During the 2002 West Coast dock shutdown, the economic loss was estimated at \$140 million per day.<sup>11</sup> A complete closure of U.S. borders to international travel and trade would be unprecedented.

<sup>8</sup>U.S. Dept. of Commerce, U.S. Census Bureau, Foreign Trade Division, *U.S. Exports of Merchandise and U.S. Imports of Merchandise*, March 2005.

<sup>9</sup>Based on U.S. Dept. of Commerce, U.S. Census Bureau, Foreign Trade Division, *U.S. Exports of Merchandise and U.S. Imports of Merchandise*, March 2005.

<sup>10</sup>Ships are the primary mode of transportation for world trade. Ships carry more than 95 percent of the U.S.' non-North American trade by weight and 75 percent by value, and 80 percent of the foreign oil imported by the U.S. Waterborne cargo contributes about 7.5 percent to the U.S. gross domestic product. In addition to its economic significance, the marine transportation system is vital for national security. The Departments of Defense and Transportation have designated 17 U.S. seaports as strategic because they are necessary for use by DOD in the event of a major military deployment. Thirteen of these ports are commercial seaports.

<sup>11</sup>Calculated from Patrick L. Anderson and Ilhan K. Geckil, *Flash Estimate: Impact of West Coast Shutdown*, Anderson Economic Group (October 15, 2002).

Modeling suggests that border closure would not decrease the total number of illnesses or deaths. Moreover, when the Nation's economic needs require the re-opening of the border, there could be widespread public confusion about the safety of people, freight, and travel. Nevertheless, our level of preparedness when a pandemic strikes and the uncertainties about the characteristics of a pandemic virus requires us to plan for this possibility. The section below describes potential alternatives and later sections identify additional research to explore the effectiveness and economic consequences of these options.

### **Alternatives to Complete Border Closure and Other Containment Options**

There are alternatives to complete border closure that may be effective in delaying the onset of a pandemic in the United States and can help minimize the risk of infection among travelers coming to the United States. These include targeted traveler restrictions to help contain the pandemic at its source, and implementation of layered, risk-based measures, including pre-departure, en route, and arrival screening and/or quarantine. While we should take measures to protect travelers and limit their ability to transmit disease, there is little benefit to trade restriction if there are adequate measures in place to limit exposure to infected individuals and potentially contaminated surfaces. Irrespective of the combination of interventions selected, our efforts should be taken collaboratively with other nations, although unilateral efforts may be necessary in extreme circumstances.

#### *Travelers*

The United States will work with the international community to implement targeted passenger travel restrictions (see Chapter 4 - International Efforts). As part of the preparedness effort, the United States will engage WHO and foreign governments to determine how countries with human outbreaks can support containment and help slow global spread of a pandemic. For example, pre-negotiated arrangements and partnerships with other countries could encourage all countries with outbreaks to rapidly restrict non-essential travel for all modes of transportation (e.g., air, vessel, and land travel) in return for technical and other forms of assistance. In addition, the United States could deny entry of travelers, or place conditions on the return of travelers from countries with outbreaks and other countries that have not instituted acceptable pre-departure screening, prohibit entry of travelers from the affected area, or continue to accept travelers with appropriate conditions from countries with outbreaks. Additional options would be considered for U.S. citizens planning to return home from affected areas, such as a voluntary quarantine to monitor for illness through one incubation period prior to departure. This could reduce risk of transmission for the United States, and help identify persons in need of medical care.

Individual screening, for influenza-like illness and risk factors for infection with a pandemic strain, of all persons entering the United States will help minimize the risk of transmission. However, such screening is challenged by a lack of sensitivity (e.g., asymptomatic infected individuals may not be detected) and specificity (e.g., many individuals with influenza-like illness will not be infected with a pandemic strain). The typical incubation period for influenza is 2 days and infected persons with influenza may be contagious for 24 hours prior to the onset of symptoms. Since some asymptomatic travelers, who are incubating influenza, may become symptomatic en route, overall screening effectiveness can be improved by adopting layered pre-departure, en route, and arrival screening measures. The policy of layered screening measures would apply to all U.S.-bound travelers from affected areas, but the characteristics of the outbreak, including the rapidity of spread, may make it necessary to implement this screening at all international airports from which U.S.-bound passengers originate. In addition, development of rapid diagnostic tests can dramatically change our ability to screen effectively.

- **Pre-departure Measures:** Effective host country health screening of all individuals prior to departure may reduce the risk of infected travelers exposing fellow travelers, aircraft and vessel crews, and others upon arrival. This is consistent with the WHO Global Influenza Preparedness Plan and with the newly revised International Health Regulations. Screening could be performed for signs of illness (e.g., temperature scanning) and for risk factors (e.g., contacts, travel history). A clear description of signs of illness and risk factors for infection with pandemic influenza will be critical to develop effective screening protocols. Significant additional personnel and resources will be needed to strengthen in-country pre-departure screening capacity, particularly in countries that are heavily affected by a pandemic. The number of infected persons traveling to the United States could also be reduced by isolating potentially exposed individuals for one incubation period prior to international travel. The need to develop pre-departure measures and identify the necessary staffing resources will apply equally to the United States when pandemic transmission occurs domestically.
- **En Route Measures:** Given the short incubation period of influenza, and the length of some international flights, one can assume that some travelers with influenza will develop their first symptoms during their journey. The training of flight and vessel crews to detect and manage ill travelers can decrease risk for others on the conveyance and permit assessment and treatment upon landing. When combined with pre-departure exit screening, this strategy would detect those who developed signs of illness while en route. Response would include moving ill persons away from other travelers, if possible, placing a surgical mask on the ill person, and emphasizing the importance of hygiene measures, such as hand washing. If a mask is not available, covering coughs and sneezes with a tissue or cloth that is disposed after use will also decrease risk. By regulation, the master of ship or commander of an aircraft destined for a U.S. port is required to report the presence of any ill persons (as defined in the regulation) or deaths on board to the nearest quarantine station at which the ship or aircraft will arrive. In its proposed rule, the Centers for Disease Control and Prevention (CDC) has proposed expanding the definition of ill persons to include additional illness criteria indicative of the presence of a quarantinable disease, such as pandemic influenza.
- **Arrival Measures:** Arrival screening may serve as an important additional layer if we cannot ensure the adequacy and effectiveness of other containment measures. It can also identify individuals who became ill during travel. Arrival screening can be imposed as a precautionary measure, irrespective of other containment measures. Travelers with influenza-like illness should be isolated and undergo diagnostic testing; other travelers may potentially be quarantined until definitive testing is complete. When developed, rapid diagnostic testing could greatly increase effectiveness of screening. These arrival procedures also provide an opportunity to educate travelers to increase their awareness of influenza symptoms and the need for seeking medical care and immediate home quarantine when compatible symptoms arise. It must be recognized that arrival screening will place additional demands on CDC Quarantine Station personnel and Customs and Border Protection officers and agents. It is critical that local quarantine plans leverage available Federal, State, and local assets to implement effective screening, quarantine, and isolation, and provide expanded access to medical treatment. Capacity could also be addressed by examining the costs and benefits of potentially funneling inbound international flights to a subset of U.S. airports. Preliminary research indicates that potentially 96 percent of all inbound

international flights arrive at 30 U.S. airports.<sup>12</sup> Additional work will be needed to explore and evaluate options with airlines, airports, and local authorities and public health professionals.

#### *Cargo and Trade Goods*

This risk of influenza transmission by cargo or trade goods, excluding live avian or animal cargo, is low. With effective protective measures for workers in specific settings, cargo shipments could continue. Because viable influenza virus may remain on surfaces for up to 48 hours, ship-borne cargo poses the lowest risk of virus transmission. Risk of transmission by or to the vessel's crew could be eliminated by confining them to the vessel and utilizing strict transmission prevention protocols with port personnel during loading/off loading operations. Given the greater speed of international air transport, additional measures may be needed for worker protection and, in some cases, to disinfect and/or isolate air cargo from a country with an outbreak.

#### *Land Borders*

Our approach to slowing the introduction of pandemic influenza through land borders will emphasize continental rather than national containment, and will respect our treaty commitments and other arrangements with Canada and Mexico. Our planning efforts with Canada and Mexico will include discussions of each country's efforts to support global containment, plans to implement travel restrictions, and commitments for rigorous screening at arrivals. Should the disease appear in Canada or Mexico, land borders would become the greatest point of vulnerability due to the high volume and nature of land border crossing. Specific measures used at land borders will depend on the temporal and geographic spread of disease and will require more intensive modeling to explore their potential effectiveness.

Unique challenges along our land borders will require significant outreach with the Canadian and Mexican governments and other stakeholders. On-time delivery of goods and workers being prevented from going to their jobs would create major challenges at land border locations, and could potentially affect the U.S. economy. On the northern border, the major manufacturing industries (e.g., automotive) would likely be adversely affected by restrictions or slow-downs at the border. On the southern border, textile and agriculture product importation could be impaired. In addition, there are a significant number of day workers that transit across the border. Therefore, planning should consider a range of alternatives, from approaches that permit the cross border flow of critical goods to complete border closure. Potentially infected illegal aliens attempting to cross between our ports of entry present another challenge and could create facility challenges related to quarantine.

Maintaining operational control of our Nation's borders is an essential function of the Department of Homeland Security (DHS). The presence of pandemic influenza in Central America or Mexico may trigger a mass migration. DHS would need to manage a large increase of additional attempted illegal entrants during a 2-month period. This spike will likely increase during a period when DHS resources are stretched due to employee absenteeism.

---

<sup>12</sup> U.S. Department of Transportation, Research and Innovative Technology Administration, Bureau of Transportation Statistics, T100 SEGMENT data, year-end second quarter 2005. (Note: includes all scheduled flights, as well as most charter, military, and private international flights).

### **Complexity of Transportation Decisions in Emergencies**

The complexities of the transportation system and its relationship with public safety, productivity, health, and the national economy require that its assets be managed wisely during any emergency. During some training exercises, emergency transportation decisions have been made without full appreciation of the resulting consequences, including serious economic implications.

Managing transportation decisions in a pandemic will require extraordinary cooperation between the varied and diverse elements of the sector. In many cases, decision makers will be simultaneously managing complex and competing interests. State and local governments, acting within their authorities, may impose restrictions or closures of transportation systems without consulting or coordinating with Federal entities. This can be in the form of State/county border closures or closure of transit systems, ports, or airports. This could have considerable impact on efforts to move patients, responders, medical personnel, critical pharmaceuticals, and essential supplies. A key role for the Federal Government will be to provide clear criteria to guide and inform State and local actions and to conduct outreach with State, community, and tribal entities to communicate a cohesive national strategy for maintaining movement of essential critical goods and services, while encouraging limitation of non-essential transportation. Closing State or local borders is highly unlikely to be cost-effective, may create significant shortages in essential commodities, and is not preferred (see also Chapter 9 - Institutions: Protecting Personnel and Ensuring Continuity of Operations).

### **Sustaining Critical Transportation Services**

Sustaining critical services during a pandemic will be crucial to keep communities functioning and emergency supplies and resources flowing. Planning efforts need to assess systemic effects (i.e., supply chain impact, just-in-time delivery, warehousing, and logistics) and support the development of contingency plans to address lack of critical services and delivery of essential commodities, such as chlorine for water purification, gasoline, food, and medical supplies.

Due to expected high absenteeism, transportation services may be limited. Interstate movement will become increasingly constrained as the pandemic peaks and local travel restrictions may increase. Passenger transportation will likely decrease as the public opts not to travel due to possible exposure. This will likely begin in international aviation, cruise ships, and highway border crossings. Once cases are present in the United States, this decrease in passenger travel will occur domestically in private automobile, aviation, mass transit, passenger rail, and motor coach travel. However, there may also be a small surge of movement into affected areas as individuals try to return home or help stranded or ill relatives. Others may attempt to temporarily relocate to less populated areas in an attempt to reduce the likelihood of infection. At the beginning of the pandemic, there will also be requests to move emergency workers, equipment, and resources. As the disease spreads to multiple urban areas, emergency transportation of supplies and personnel could decrease because resources will be needed locally.

There is a need to examine critical junctures where the increase in demand for essential commodities and emergency services intersect with a large reduction in workforce due to absenteeism. Identifying these junctures will enable the sector to focus preparedness efforts on areas of the transportation system that will be under the greatest strain during a pandemic.

**Emergency Transportation Services**

A pandemic outbreak in the United States will result in the activation of the *National Response Plan* (NRP) and Emergency Support Function #1 - Transportation (ESF #1) to coordinate Federal support for emergency transportation services. Activation under pandemic conditions will be considerably more challenging, with many urban areas simultaneously affected for a sustained period of time, as opposed to historically localized and short-duration activations following natural disasters.

Management of a pandemic response during NRP activation will be driven by decisions at the State and local level. Transportation response in such an emergency will be vital, with the Federal role focusing on coordination and communication across the sector, in addition to its emergency transportation services under the NRP. Balancing the demands of a pandemic in the NRP context with existing resources and maintaining response capacity for other disasters or terrorist incidents will be a priority focus.

Another key area is patient movement, which is coordinated primarily by Emergency Support Function #8 - Public Health and Medical Services (ESF #8). It is unlikely that patient movement will be similar in scope and resource requirements to the patient evacuation that has occurred during major hurricanes. Patient movement is discussed in greater detail under Chapter 6 - Protecting Human Health.

**Transportation and Border Preparedness**

An influenza pandemic poses significant challenges that must be addressed in the border and transportation planning process. All private sector, State and local entity, and Federal Government plans need to address the following four key areas: (1) maintaining situational awareness; (2) rapidly containing cases or initial outbreaks; (3) sustaining critical transportation and border services; and (4) recovery of the transportation system.

*Maintaining Situational Awareness*

Due to the complexity of transportation and border decisions and the dynamic effect of local decisions on the national network, it will be essential to enhance and maintain situational awareness across the sector. Plans should address:

- Ensuring adequate information sharing, analysis, and coordination among the private sector, State and local governments, the Federal Government, and international partners.
- Providing updates on the status of the transportation system, including operations and closures across the country.
- Maintaining awareness of public health measures under consideration that may have transportation implications, such as vaccine/antiviral distribution, need for food, and other essential services during quarantines, school closures, “snow days,” travel restrictions, or other measures for social distancing.
- Establishing clear notification protocols to keep the private sector, State, local, and tribal governments, and the Federal Government informed of the pandemic threat, including early warning signs and potential cases.



*Rapidly Containing Cases or Initial Outbreak*

Early transportation containment measures are more effective in slowing the spread of a pandemic if they are part of a larger comprehensive strategy that incorporates other measures, such as social distancing, isolation, vaccination, and antiviral medications. New models are being developed that will provide additional information on the potential benefits of containment options, including domestic travel restrictions. Plans should address:

- The need for close coordination between public health and transportation planners and local, State, and tribal entities, and the Federal Government to understand and integrate emerging modeling on border and transportation decisions to delay the spread of a pandemic and potential health benefits, social and economic consequences, and operational feasibility.
- Developing a range of transportation and border options based on the various stages of a pandemic. These options should include a full range of voluntary and mandatory travel restrictions, identify costs and benefits, and trigger points to use and remove measures.
- Border entry and exit policies for travelers and cargo, and detailed protocols for air, maritime, and land border ports of entry.
- Identifying and mitigating workforce risks and concerns regarding potential exposure, establishing risk-based priorities for protective equipment and limited countermeasures, acquiring/distributing equipment and countermeasures, and conducting outreach with workers.

*Sustaining Critical Transportation and Border Service*

The private sector, State and local entities, and the Federal Government all have key roles in sustaining critical services, delivering essential commodities, and supporting public health recommendations (e.g., vaccine distribution, social distancing measures). Plans should address:

- Identifying and maintaining essential services (e.g., maintaining the National Airspace System) given anticipated high rates of absenteeism rates and surges in demand for emergency medical supplies and services.
- Developing and implementing screening protocols for cargo and travelers and decontamination protocols for transportation and border personnel, assets, and facilities.
- Assessing systemic effects on the transportation system (e.g., supply chain impact, just-in-time delivery, warehousing, and logistics) and borders.
- Developing contingency plans to address lack of essential services, including delivery of essential commodities such as chlorine for water purification, gasoline, food, fuel, and medical supplies.
- Assessing and mitigating workforce risks and concerns regarding potential exposure, establishing risk-based prioritization for countermeasures, acquiring/distributing protective equipment and supplies, and conducting outreach.
- Addressing the need to provide security to protect shipments of critical, high-demand supplies (e.g., vaccine or antiviral medications and shipments of food and fuel).

*Recovery of the Transportation System*

Returning the transportation system to pre-pandemic conditions may be a complex and challenging task. Confidence in safety will need to be restored to travelers and transportation workers, and transportation assets may require deferred maintenance and possibly decontamination/disinfection/cleaning before being returned to service. Reprioritization of suspended or in-transit commodities may be required and some carriers may have permanently ceased operations due to the operational/financial burdens caused by the pandemic.

**Roles and Responsibilities**

The Federal Government, State and local governments, and the private sector, all have important and interdependent roles in transportation-related decisions to prepare for, respond to, and recover from a pandemic. Effective management of the Nation's transportation system in a pandemic will require a highly coordinated response from across the transportation sector. A pandemic's impact on the health and welfare of our citizens and the condition of our national economy will be directly affected by the degree of integration and coordination of the different levels of government and the private sector during the crises.

State and local governments have primary responsibility for detecting and responding to disease outbreaks and implementing measures to minimize the health, social, and economic consequences. The transportation decisions made at critical junctures and in multiple metropolitan areas can have cascading effects on the rest of the system and on the Nation's ability to keep supplies and services operational. The potentially catastrophic nature of a pandemic will likely overwhelm local and State capabilities. Federal agencies will be called upon to provide additional support, but even these resources may be overwhelmed at the peak of a pandemic.

**The Federal Government**

The Federal Government will use all capabilities within its authority to support private sector and State and local transportation preparedness, response, and recovery efforts. The Federal Government will increase readiness to sustain critical Federal transportation and border services during a pandemic and provide emergency transportation services under the NRP.

The Federal Government will incorporate the following elements in departmental preparedness plans: (1) carrying out assigned responsibilities, and exercising authorities where necessary, to ensure a comprehensive and coordinated national effort; (2) supporting private sector and State and local government transportation and border preparedness and response, including providing clear guidance to State and local authorities; (3) sustaining critical Federal transportation and border services; and (4) increasing their ability to provide emergency transportation under the NRP.

The Implementation Plan (Plan) outlines issues related to transportation and border preparedness that intersect with the missions and responsibilities of a number of key Federal departments and will require joint planning and close collaboration. To coordinate the Federal Government's development and execution of the Plan, the Department of Homeland Security will lead border preparedness, surveillance, and response and the Department of Transportation will lead overall transportation preparedness, surveillance, and response. Both departments will work closely to ensure coordination across these areas and with relevant departments and stakeholders.



Department of Homeland Security: DHS is responsible for ensuring integrity of the Nation's infrastructure, domestic security, providing support to entry and exit screening for pandemic influenza at the borders, facilitating coordination for the overall response to a pandemic, and the provision of a common operating picture for all departments and agencies of the Federal Government. DHS is also responsible for securing the Nation's borders and facilitating legitimate trade and travel through U.S. ports of entry.

DHS supports coordination of the NRP, which is the primary mechanism for coordination of the Federal Government response to Incidents of National Significance, and will form the basis of the Federal pandemic response. The NRP provides an organizing framework for coordinating a variety of support areas, including transportation, mass care, and public affairs, which are led by other Federal departments (see Chapter 3 for more detail). DHS will collaborate with other departments on transportation and border decisions, including the ability to control the spread of a pandemic (Department of Health and Human Services (HHS), Department of Agriculture (USDA), Department of Transportation (DOT), and Department of the Interior (DOI)), understand social and economic consequences (Department of Commerce (DOC), DOT, Department of the Treasury (Treasury), Department of State (DOS), HHS, USDA, DHS components, DOI, and key stakeholders), international and domestic implications (DOS, DOT, DOC, DHS components, and key stakeholders), and to obtain the economic and operational feasibility of actions (DOT, DOC, DHS components, and key stakeholders).

Department of Health and Human Services: HHS's primary responsibilities are to protect the health of all U.S. citizens and provide essential human services. With respect to transportation and borders, HHS will be involved in entry and exit screening and, in consultation with Department of Labor (DOL), protecting the health of transportation and border workers who are implementing measures to limit spread. HHS will support rapid containment of localized outbreaks domestically. HHS will provide recommendations to State, local, tribal, and private sector entities on the ability of transportation restrictions to limit the spread of a pandemic, patient movement, and plans for traveler screening, isolation, and quarantine at ports of entry. In addition, HHS and USDA are responsible for the exclusion and seizure of infectious animals or animal products. HHS exercises this authority with respect to human health, while USDA exercises this authority with respect to animal health.

Department of Transportation: DOT will implement priorities to maintain essential functions of the national transportation system, and provide emergency management and guidance for civil transportation resources and systems. In its role in the global transportation network, DOT will conduct outreach with its established public and private stakeholders — strategically coordinating with international, domestic, and other Federal Government participants, consistent with its responsibilities under the NRP in support of DHS. DOT will consider the short- and long-term economic impacts of a pandemic on the transportation sector in order to develop strategies that might prevent disruption of transportation services.

Department of Defense: DOD's primary responsibilities are those actions required to protect DOD forces, maintain operational readiness, and sustain critical military missions. DOD will increase its readiness to sustain critical DOD services to support the NRP and elements of the U.S. Government's international response. DOD can provide additional support to the extent that DOD's National Security readiness is not compromised.

When directed by the Secretary of Defense in accordance with law, DOD will collaborate with DOS and DOT in building international partnerships and enhancing their transportation capability. Once an

outbreak occurs, DOD may play a role, consistent with existing agreements and legal authorities, in implementation of movement controls, controlling movement into and out of areas/borders with affected populations, and assisting in the transportation/movement of rapid response teams, medical countermeasures (antiviral medications and vaccines, if available), and logistical support materials to infected and at-risk populations according to established plan and guidelines when other public or private sector assets are not available.

Department of State: DOS will facilitate international cooperation and coordination and keep foreign governments, international businesses and organizations, and the public informed of U.S. policies and measures affecting travel and transportation. DOS will also communicate travel risk information to U.S. citizens residing and traveling abroad so as to allow them to make informed decisions and plans. In the event of U.S. Government-sponsored evacuations, DOS will provide appropriate assistance to U.S. citizens overseas.

Department of Agriculture: USDA is responsible for protecting the Nation's livestock, including poultry, from exotic or foreign animal diseases, such as highly pathogenic avian influenza. With respect to transportation and borders, USDA will determine, based on the country of origin and other factors, which articles, live animals, or animal products have the potential for introducing or spreading an exotic disease and will establish restrictions or exclusions on their importation into, and/or movements within, the United States. If live animals are not excluded from importation, USDA determines which live animals must undergo USDA-supervised quarantine and health examination prior to final entry into the United States.

Department of the Interior: DOI is responsible for permitting and inspection of wildlife and wildlife products in trade into and out of the United States. With respect to transportation and borders, DOI will work in partnership with DHS, USDA, and DOS to enforce and publicize wildlife border controls and, if appropriate, utilize its own permitting authorities to restrict the import or export of wild birds.

Department of Labor: DOL's primary responsibilities are those actions required to protect the health and safety of workers, including communication of information related to pandemic influenza to workers and employers, and other relevant activities.

### **State, Local, and Tribal Entities**

State and community pandemic preparedness plans should address key transportation issues and outline social distancing measures and strategies to mitigate consequences. States will face challenges in availability of essential commodities, demands for services that exceed capacity, and public pressure to restrict transportation in ways that may hinder economic sustainment and delivery of emergency services and supplies.

State, local, and tribal entities should develop and exercise pandemic influenza plans that address transportation's role in maintaining State and community functions, including delivery of essential services, containment strategies, providing critical services to citizens, support for public health measures, and other key regional or local issues. State and local governments should involve transportation and health professionals to identify transportation options, consequences, and implications. Transportation and border plans should be integrated as part of a comprehensive State plan that addresses the full range of pandemic preparedness (i.e., public health, animal health, protecting institutions, and law enforcement, public safety, and security). States will also need to coordinate closely with neighboring States/regions and the Federal Government to assess the interdependencies of local, State, and national decisions on the viability of the sector.

## The Private Sector and Critical Infrastructure Entities

The private sector will play an integral role in preparedness before a pandemic begins and should be part of the national response. As they prepare, respond, sustain, and recover from a pandemic, transportation owners/operators will strive to maintain as close to normal operations as possible within the constraints of a pandemic.

The private sector should develop pandemic influenza plans that identify challenges and outline strategies to sustain core transportation and border functions and mitigate economic consequences. Entities should engage the full spectrum of preparedness planning to maintain essential services as close to normal operations as possible within the constraints of a pandemic.

## Individuals and Families

It is important for U.S. citizens to recognize and understand the degree to which their actions will govern the course of a pandemic. The success or failure of border and transportation measures are ultimately dependent upon the acts of individuals, and the collective response of 300 million U.S. citizens will significantly influence the shape of the pandemic and its medical, social, and economic outcomes (see *Individual, Family, and Community Response to Pandemic Influenza* between Chapters 5 and 6). Individuals will, in general, respond to a pandemic and to public health interventions in ways that they perceive to be congruent with their interests and their instinct for self-preservation, and border and transportation authorities should tailor their risk communication campaigns and interventions accordingly. This will directly affect the willingness of the public to participate in travel-related screening and support voluntary domestic and international travel limitations.

## International Partners

The response to a pandemic will be a global one, necessitating action by international organizations and governments. DOT and DHS have relationships with many international organizations, governments, and the private sector due to the global nature of today's economy. In close coordination with DOS, DOT and DHS will leverage their international relationships to assist in ensuring the continued movement of goods, services, and people (see Chapter 4 — International Efforts).

## Actions and Expectations

### 5.1. Pillar One: Preparedness and Communication

This section provides an overview of planning expectations across the transportation and border sector (i.e., the private sector, State and local entities, and the Federal Government) and a detailed discussion of actions the Federal Government will take to support preparedness. Effective planning for a pandemic will require the development of plans, procedures, policies, and training to prepare for, respond to, and recover from a pandemic.

#### a. Planning for a Pandemic

- 5.1.1. **Develop Federal implementation plans to support the *National Strategy for Pandemic Influenza*, to include all components of the U.S. Government and to address the full range of consequences of a pandemic.**

- 5.1.1.1. DHS and DOT shall establish an interagency transportation and border preparedness working group, including DOS, HHS, USDA, DOD, DOL, and DOC as core members, to develop planning assumptions for the transportation and border sectors, coordinate preparedness activities by mode, review products and their distribution, and develop a coordinated outreach plan for stakeholders, within 6 months. Measure of performance: interagency working group established, planning assumptions developed, preparedness priorities and timelines established by mode, and outreach plan for stakeholders in place.
- 5.1.1.2. HHS and DHS, in coordination with the National Economic Council (NEC), DOD, DOC, U.S. Trade Representative (USTR), DOT, DOS, USDA, Treasury, and key transportation and border stakeholders, shall establish an interagency modeling group to examine the effects of transportation and border decisions on delaying spread of a pandemic, and the associated health benefits, the societal and economic consequences, and the international implications, within 6 months. Measure of performance: interagency working group established, planning assumptions developed, priorities established, and recommendations made on which models are best suited to address priorities.
- 5.1.1.3. DHS and DOT, in coordination with DOD, HHS, USDA, Department of Justice (DOJ), and DOS, shall assess their ability to maintain critical Federal transportation and border services (e.g., sustain National Air Space, secure the borders) during a pandemic, revise contingency plans, and conduct exercises, within 12 months. Measure of performance: revised contingency plans in place at specified Federal agencies that respond to both international and domestic outbreaks and at least two interagency exercises carried out to test the plans.
- 5.1.1.4. DHS and DOT, in coordination with DOD, HHS, USDA, USTR, DOL, and DOS, shall develop detailed operational plans and protocols to respond to potential pandemic-related scenarios, including inbound aircraft/vessel/land border traffic with suspected case of pandemic influenza, international outbreak, multiple domestic outbreaks, and potential mass migration, within 12 months. Measure of performance: coordinated Federal operational plans that identify actions, authorities, and trigger points for decision making and are validated by interagency exercises.
- 5.1.1.5. DOD, in coordination with DHS, DOT, DOJ, and DOS, shall conduct an assessment of military support related to transportation and borders that may be requested during a pandemic and develop a comprehensive contingency plan for Defense Support to Civil Authorities, within 18 months. Measure of performance: Defense Support to Civil Authorities plan in place that addresses emergency transportation and border support.
- 5.1.1.6. DOT, in coordination with DHS, DOD, DOJ, HHS, DOL, and USDA, shall assess the Federal Government's ability to provide emergency transportation support during a pandemic under NRP ESF #1 and develop a contingency plan, within 18 months. Measure of performance: completed contingency plan that includes options for increasing transportation capacity, the potential need for military

support, improved shipment tracking, potential need for security and/or waivers for critical shipments, incorporation of decontamination and workforce protection guidelines, and other critical issues.

**5.1.2. Continue to work with States, localities, and tribal entities to establish and exercise pandemic response plans.**

- 5.1.2.1. DHS and HHS, in coordination with DOT and USDA, shall review existing grants or Federal funding that could be used to support transportation and border-related pandemic planning, within 4 months. Measure of performance: all State, local, and tribal governments are in receipt of, or have access to, guidance for grant applications.
- 5.1.2.2. DOT, in coordination with DHS, HHS, and transportation stakeholders, shall convene a series of forums with governors and mayors to discuss transportation and border challenges that may occur in a pandemic, share approaches, and develop a planning strategy to ensure a coordinated national response, within 12 months. Measure of performance: strategy for coordinated transportation and border planning is developed and forums initiated.
- 5.1.2.3. DOT and DHS, in coordination with HHS, USDA, and transportation stakeholders, shall develop planning guidance and materials for State, local, and tribal governments, including scenarios that highlight transportation and border challenges and responses to overcome those challenges, and an overview of transportation roles and responsibilities under the NRP, within 12 months. Measure of performance: State, local, and tribal governments have received or have access to tailored guidance and planning materials.
- 5.1.2.4. State, community, and tribal entities, in coordination with neighboring States and communities, the private sector, transportation providers, and health professionals, should develop transportation contingency plans that identify a range of options to respond to different stages of a pandemic, including support for public health containment strategies, maintaining State and community functions, transportation restriction options and consequences, delivery of essential goods and services, and other key regional or local issues, within 18 months.
- 5.1.2.5. DHS and DOT, in coordination with DOD and States, shall develop a range of options to cope with potential shortages of commodities and demand for essential services, such as building reserves of essential goods, within 20 months. Measure of performance: options developed and available for State, local, and tribal governments to refine and incorporate in contingency plans.

**5.1.3. Continue to work with States, localities, and tribal entities to integrate non-health sectors, including the private sector and critical infrastructure entities, in these planning efforts.**

- 5.1.3.1. DHS, in coordination with DOT, HHS, and USDA, shall conduct tabletop discussions and other outreach with private sector transportation and border

entities to provide background on the scope of a pandemic, to assess current preparedness, and jointly develop a planning guide, within 8 months. Measure of performance: private sector transportation and border entities have coordinated Federal guidance to support pandemic planning, including a planning guide that addresses unique border and transportation challenges by mode., within 8 months. Measure of performance: private sector transportation and border entities have coordinated Federal guidance to support pandemic planning, including a planning guide that addresses unique border and transportation challenges by mode.

- 5.1.3.2. DHS, in coordination with DOT, HHS, DOC, Treasury, and USDA, shall work with the private sector to identify strategies to minimize the economic consequences and potential shortages of essential goods (e.g., food, fuel, medical supplies) and services during a pandemic, within 12 months. Measure of performance: the private sector has strategies that can be incorporated into contingency plans to mitigate consequences of potential shortages of essential goods and services.
- 5.1.3.3. Private sector transportation and border entities, in coordination with States and customers, should develop pandemic influenza plans that identify challenges and outline strategies to sustain core functions, essential services, and mitigate economic consequences, within 16 months.

***b. Communicating Expectations and Responsibilities***

**5.1.4. Provide guidance to the private sector and critical infrastructure entities on their role in the pandemic response, and considerations necessary to maintain essential services and operations despite significant and sustained worker absenteeism.**

- 5.1.4.1. HHS, in coordination with DHS, DOT, and DOL, shall establish workforce protection guidelines and develop targeted educational materials addressing the risk of contracting pandemic influenza for transportation and border workers, within 6 months. Measure of performance: guidelines and materials developed that meet the diverse needs of border and transportation workers (e.g., customs officers or agents, air traffic controllers, train conductors, dock workers, flight attendants, transit workers, ship crews, and interstate truckers).
- 5.1.4.2. DHS, in coordination with DOT, DOL, Office of Personnel Management (OPM), and DOS, shall disseminate workforce protection information to stakeholders, conduct outreach with stakeholders, and implement a comprehensive program for all Federal transportation and border staff within 12 months. Measure of performance: 100 percent of workforce has or has access to information on pandemic influenza risk and appropriate protective measures.
- 5.1.4.3. HHS, in coordination with DHS, DOT, DOD, Environmental Protection Agency (EPA), and transportation and border stakeholders, shall develop and disseminate decontamination guidelines and timeframes for transportation and border assets and facilities (e.g., airframes, emergency medical services transport vehicles, trains, trucks, stations, port of entry detention facilities) specific to



pandemic influenza, within 12 months. Measure of performance: decontamination guidelines developed and disseminated through existing DOT and DHS channels.

## **5.2. Pillar Two: Surveillance and Detection**

Early warning of a pandemic is critical to being able to rapidly employ resources to contain the spread of the virus. An effective detection system will save lives by allowing us to activate our response plans before the arrival of a pandemic virus in the United States. DHS will work closely with DOT, HHS, USDA, and DOS to develop and be prepared to implement screening protocols to enhance pre-departure, en route, and arrival screening at the U.S. border (land, air, and sea) for potentially infected travelers, animals, and other cargo.

### ***a. Ensuring Rapid Reporting of Outbreaks***

**5.2.1. Advance mechanisms for “real-time” clinical surveillance in domestic acute care settings such as emergency departments, intensive care units, and laboratories to provide local, State, and Federal public health officials with continuous awareness of the profile of illness in communities, and leverage all Federal medical capabilities, both domestic and international, in support of this objective.**

5.2.1.1. HHS and USDA, in coordination with DHS, DOT, DOS, DOD, DOI, and State, local, and international stakeholders, shall review existing transportation and border notification protocols to ensure timely information sharing in cases of quarantinable disease, within 6 months. Measure of performance: coordinated, clear interagency notification protocols disseminated and available for transportation and border stakeholders.

**5.2.2. Develop and deploy rapid diagnostics with greater sensitivity and reproducibility to allow onsite diagnosis of pandemic strains of influenza at home and abroad, in humans, to facilitate early warning, outbreak control, and targeting of antiviral therapy.**

5.2.2.1. DHS, in coordination with HHS and DOD, shall deploy human influenza rapid diagnostic tests with greater sensitivity and specificity at borders and ports of entry to allow real-time health screening, within 12 months of development of tests. Measure of performance: diagnostic tests, if found to be useful, are deployed; testing is integrated into screening protocols to improve screening at the 20-30 most critical ports of entry.

### ***b. Using Surveillance to Limit Spread***

**5.2.3. Develop mechanisms to rapidly share information on travelers who may be carrying or may have been exposed to a pandemic strain of influenza, for the purposes of contact tracing and outbreak investigation.**

5.2.3.1. DHS, in coordination with HHS, DOT, DOS, and DOD, shall work closely with domestic and international air carriers and cruise lines to develop and implement protocols (in accordance with U.S. privacy law) to retrieve and

rapidly share information on travelers who may be carrying or may have been exposed to a pandemic strain of influenza, within 6 months. Measure of performance: aviation and maritime protocols implemented and information on potentially infected travelers available to appropriate authorities.

**5.2.4. Develop and exercise mechanisms to provide active and passive surveillance during an outbreak, both within and beyond our borders.**

- 5.2.4.1. HHS, in coordination with DHS, DOT, DOS, DOC, and DOJ, shall develop policy recommendations for aviation, land border, and maritime entry and exit protocols and/or screening and review the need for domestic response protocols or screening within 6 months. Measure of performance: policy recommendations for response protocols and/or screening.
- 5.2.4.2. HHS, DHS, and DOT, in coordination with DOS, DOC, Treasury, and USDA, shall develop policy guidelines for international and domestic travel restrictions during a pandemic based on the ability to delay the spread of disease and the resulting health benefits, associated economic impacts, international implications, and operational feasibility, within 8 months. Measure of performance: interagency travel curtailment policy guidelines developed that address both voluntary and mandatory travel restrictions.
- 5.2.4.3. DOS, in coordination DHS, DOT, and HHS, in consultation with aviation, maritime, and tourism industry stakeholders as appropriate, and working with international partners and through international organizations as appropriate, shall promote the establishment of arrangements through which countries would: (1) voluntarily limit travel if affected by outbreaks of pandemic influenza; and (2) establish pre-departure screening protocols for persons with influenza-like illness, within 16 months. Measure of performance: arrangements for screening protocols are negotiated.
- 5.2.4.4. DOS and HHS, in coordination with DHS, DOT, and transportation and border stakeholders, shall assess and revise procedures to issue travel information and advisories related to pandemic influenza, within 12 months. Measure of performance: improved interagency coordination and timely dissemination of travel information to stakeholders and travelers.
- 5.2.4.5. DOT and DHS, in coordination with HHS, DOD, DOS, airlines/air space users, the cruise line industry, and appropriate State and local health authorities, shall develop protocols<sup>13</sup> to manage and/or divert inbound international flights and vessels with suspected cases of pandemic influenza that identify roles, actions, relevant authorities, and events that trigger response, within 12 months. Measure of performance: interagency response protocols for inbound flights completed and disseminated to appropriate entities.

---

<sup>13</sup> Protocols will be revised as new rapid diagnostic tests become available.

---

<sup>14</sup> Protocols will be revised as new rapid diagnostic tests become available.



- 
- 5.2.4.6. HHS, in coordination with DHS, DOT, DOS, DOD, air carriers/air space users, the cruise line industry, and appropriate State and local health authorities, shall develop en route protocols for crewmembers onboard aircraft and vessels to identify and respond to travelers who become ill en route and to make timely notification to Federal agencies, health care providers, and other relevant authorities, within 12 months. Measure of performance: protocols developed and disseminated to air carriers/air space users and cruise line industry.
- 5.2.4.7. DHS, DOT, and HHS, in coordination with transportation and border stakeholders, and appropriate State and local health authorities, shall develop aviation, land border, and maritime entry and exit protocols and/or screening protocols,<sup>14</sup> and education materials for non-medical, front-line screeners and officers to identify potentially infected persons or cargo, within 10 months. Measure of performance: protocols and training materials developed and disseminated.
- 5.2.4.8. DHS and HHS, in coordination with DOT, DOJ, and appropriate State and local health authorities, shall develop detection, diagnosis, quarantine, isolation, EMS transport, reporting, and enforcement protocols and education materials for travelers, and undocumented aliens apprehended at and between Ports of Entry, who have signs or symptoms of pandemic influenza or who may have been exposed to influenza, within 10 months. Measure of performance: protocols developed and distributed to all ports of entry.
- 5.2.4.9. DHS, in coordination with DOS, HHS, Treasury, and the travel and trade industry, shall tailor existing automated screening programs and extended border programs to increase scrutiny of travelers and cargo based on potential risk factors (e.g., shipment from or traveling through areas with pandemic outbreaks) within 6 months. Measure of performance: enhanced risk-based screening protocols implemented.
- 5.2.4.10. HHS, DHS, and DOT, in coordination with DOS, State, community and tribal entities, and the private sector, shall develop a public education campaign on pandemic influenza for travelers, which raises general awareness prior to a pandemic and includes messages for use during an outbreak, within 15 months. Measure of performance: public education campaign developed on how a pandemic could affect travel, the importance of reducing non-essential travel, and potential screening measures and transportation and border messages developed based on pandemic stages.
- 5.2.5. Develop screening and monitoring mechanisms and agreements to appropriately control travel and shipping of potentially infected products to and from affected regions if necessary, and to protect unaffected populations.**
- 5.2.5.1. HHS and DHS, in coordination with DOS, DOT, DOD, DOL, and international and domestic stakeholders, shall develop vessel, aircraft, and truck cargo protocols to support safe loading and unloading of cargo while preventing transmission of influenza to crew or shore-side personnel, within 12 months.
-

- Measure of performance: protocols disseminated to minimize influenza spread between vessel, aircraft, and truck operators/crews and shore-side personnel.
- 5.2.5.2. USDA, in coordination with DHS, DOI, and HHS, shall review the process for withdrawing permits for importation of live avian species or products and identify ways to increase timeliness, improve detection of high-risk importers, and increase outreach to importers and their distributors, within 6 months. Measure of performance: revised process for withdrawing permits of high-risk importers.
- 5.2.5.3. USDA, in coordination with DOI, DHS, shall enhance protocols at air, land, and sea ports of entry to identify and contain animals, animal products, and/or cargo that may harbor viruses with pandemic potential and review procedures to quickly impose restrictions, within 6 months. Measure of performance: risk-based protocols established and in use.
- 5.2.5.4. USDA, in coordination with DHS, shall review the protocols, procedures, and capacity at animal quarantine centers to meet the requirements outlined in Part 93 of Title 9 of the Code of Federal Regulations, within 4 months. Measure of performance: procedures in place to respond effectively and efficiently to the arrival of potentially infected avian species, including provisions for adequate quarantine surge capacity.
- 5.2.5.5. USDA, in coordination with DHS, DOJ, and DOI, shall enhance risk management and anti-smuggling activities to prevent the unlawful entry of prohibited animals, animal products, wildlife, and agricultural commodities that may harbor influenza viruses with pandemic potential, and expand efforts to investigate illegal commodities, block illegal importers, and increase scrutiny of shipments from known offenders, within 9 months. Measure of performance: plan developed to decrease smuggling and further distribution of prohibited agricultural commodities and products with influenza risk.
- 5.2.5.6. USDA, DHS, and DOI, in coordination with DOS, HHS, and DOC, shall conduct outreach and expand education campaigns for the public, agricultural stakeholders, wildlife trade community, and cargo and animal importers/exporters on import and export regulations and influenza disease risks, within 12 months. Measure of performance: 100 percent of key stakeholders are aware of current import and export regulations and penalties for non-compliance.

### **5.3. Pillar Three: Response and Containment**

As the threat of a pandemic increases, the United States will implement incremental, risk-based measures at ports of entry and require similar pre-departure measures at select foreign points of embarkation. Regardless of where an outbreak occurs, the U.S. Government will use its authorities and resources to support rapid containment – whether working with international partners to contain overseas outbreaks or supporting State, local, or private sector efforts to contain domestic outbreaks. DHS should work with DOS, DOT, HHS, Treasury, and USDA to implement risk-based measures to slow the spread of a pandemic, minimize social and economic

consequences both internationally and domestically, and ensure operational feasibility. Following is a range of options that will be considered and the agency or agencies responsible for implementation (see also Chapter 4 — International Efforts).

In support of DHS, DOT serves as the coordinator and primary agency for ESF #1. This support function is designed to provide transportation support to assist in domestic incident management and coordinate the recovery, restoration, and safety/security of the transportation sector. Under the NRP, other support agencies include USDA, DOC, DOD, Department of Energy (DOE), DHS, DOI, DOJ, DOS, General Services Administration (GSA), and the U.S. Postal Service.

#### ***a. Containing Outbreaks***

##### **5.3.1. Encourage all levels of government, domestically and globally, to take appropriate and lawful action to contain an outbreak within the borders of their community, province, state, or nation.**

- 5.3.1.1. DOS and DHS, in coordination with DOT, DOC, HHS, Treasury, and USDA, shall work with foreign counterparts to limit or restrict travel from affected regions to the United States, as appropriate, and notify host government(s) and the traveling public. Measure of performance: measures imposed within 24 hours of the decision to do so, after appropriate notifications made.
- 5.3.1.2. DOS, in coordination with DOT, HHS, DHS, DOD, air carriers, and cruise lines, shall work with host countries to implement agreed upon pre-departure screening based on disease characteristics and availability of rapid detection methods and equipment. Measure of performance: screening protocols agreed upon and put in place in countries within 24 hours of an outbreak.
- 5.3.1.3. DOS, in coordination with HHS, DHS, and DOT, shall offer transportation-related technical assistance to countries with outbreaks. Measure of performance: countries with outbreaks receive U.S. offer of technical support within 36 hours of an outbreak.
- 5.3.1.4. DHS, in coordination with DOS, USDA and DOI, shall provide countries with guidance to increase scrutiny of cargo and other imported items through existing programs, such as the Container Security Initiative, and impose country-based restrictions or item-specific embargoes. Measure of performance: guidance, which may include information on restrictions, is provided for increased scrutiny of cargo and other imported items, within 24 hours upon notification of an outbreak
- 5.3.1.5. DHS, in coordination with DOT, HHS, DOS, DOD, USDA, appropriate State and local authorities, air carriers/air space users, airports, cruise lines, and seaports, shall implement screening protocols at U.S. ports of entry based on disease characteristics and availability of rapid detection methods and equipment. Measure of performance: screening implemented within 48 hours upon notification of an outbreak.

- 5.3.1.6. DHS, in coordination with DOT, HHS, USDA, DOD, appropriate State, and local authorities, air carriers and airports, shall consider implementing response or screening protocols at domestic airports and other transport modes as appropriate, based on disease characteristics and availability of rapid detection methods and equipment. Measure of performance: screening protocols in place within 24 hours of directive to do so.

**5.3.2. Where appropriate, use governmental authorities to limit non-essential movement of people, goods, and services into and out of areas where an outbreak occurs.**

- 5.3.2.1. DHS, DOS, and HHS, in coordination with DOT and USDA, shall issue travel advisories/public announcements for areas where outbreaks have occurred and ensure adequate coordination with appropriate transportation and border stakeholders. Measure of performance: coordinated announcements and warnings developed within 24 hours of becoming aware of an outbreak and timely updates provided as required.
- 5.3.2.2. DHS and DOT, in coordination with DOS and Treasury, and international and domestic stakeholders, shall consider activating plans, consistent with international law, to selectively limit or deny entry to U.S. airspace, U.S. territorial seas (12 nautical miles offshore), and ports of entry, including airports, seaports, and land borders and/or restrict domestic transportation, based on risk, public health benefits, and economic impacts. Measure of performance: measures implemented within 6 hours of decision to do so.
- 5.3.2.3. DHS, in coordination with USDA, DOS, DOC, DOI, and shippers, shall rapidly implement and enforce cargo restrictions for export or import of potentially contaminated cargo, including embargo of live birds, and notify international partners/shippers. Measure of performance: measures implemented within 6 hours of decision to do so

***b. Sustaining Infrastructure, Essential Services, and the Economy***

**5.3.3. Encourage the development of coordination mechanisms across American industries to support the above activities during a pandemic.**

- 5.3.3.1. HHS and USDA, in coordination with DHS, DOT, DOS, and DOI, shall provide emergency notifications of probable or confirmed cases and/or outbreaks to key international, Federal, State, local, and tribal transportation and border stakeholders through existing networks. Measure of performance: emergency notifications occur within 24 hours or less of events of probable or confirmed cases or outbreaks.
- 5.3.3.2. DHS and DOT, in coordination with DOS, shall gather information from the private sector, international, State, local, and tribal entities, and transportation associations to assess and report the status of the transportation sector. Measure of performance: decision makers have current and accurate information on the status of the transportation sector.

**5.3.4. Provide guidance to activate contingency plans to ensure that personnel are protected, that the delivery of essential goods and services is maintained, and that sectors remain functional despite significant and sustained worker absenteeism.**

- 5.3.4.1. DHS and DOT shall notify border and transportation stakeholders and provide recommendations to implement contingency plans and/or use authorities to restrict movement based on ability to limit spread, economic and societal consequences, international considerations, and operational feasibility. Measure of performance: border and transportation stakeholders receive notification and recommendations within no more than 24 hours (depending on urgency) of an outbreak or significant development that may warrant a change in stakeholder actions or protective measures.
- 5.3.4.2. DHS and DOT shall consider activating contingency plans as needed to ensure availability of Federal personnel at more critical facilities and higher volume crossings or hubs. Measure of performance: Federal services sustained at high-priority/high-volume facilities.
- 5.3.4.3. DHS, if needed, will implement contingency plans to maintain border control during a period of pandemic influenza induced mass migration. Measure of performance: contingency plan activated within 24 hours of notification.
- 5.3.4.4. DHS and DOT, in coordination with USDA, DOI, DOC, and DOS, shall consult with the domestic and international travel industry (e.g., carriers, hospitality industry, and travel agents) and freight transportation partners to discuss travel and border options under consideration and assess potential economic and international ramifications prior to implementation. Measure of performance: initial stakeholder contacts and solicitation for inputs conducted within 48 hours of an outbreak and re-established if additional countries affected.
- 5.3.4.5. DOT shall issue safety-related waivers as needed, to facilitate efficient movement of goods and people during an emergency, balancing the need to expedite services with safety, and States should consider waiving state-specific regulatory requirements, such as size and weight limits and convoy registration. Measure of performance: all regulatory waivers as needed balance need to expedite services with safety.
- 5.3.4.6. DOJ and DHS shall protect targeted shipments of critical supplies and facilities by providing limited Federal security forces under Emergency Support Function #13 - Public Safety and Security (ESF #13) of the NRP, as needed. Measure of performance: all appropriate Federal, State, local, and tribal requests for Federal law enforcement and security assistance met via activation of ESF #13 of the NRP. (See also Chapter 8 - Law Enforcement, Public Safety, and Security.)
- 5.3.4.7. DHS, in coordination with DOS, DOT, DOD, and the Merchant Marine, shall work with major commercial shipping fleets and the international community to ensure continuation of maritime transport and commerce, including activation of plans, as needed, to provide emergency medical support to crews of vessels that are not capable of safe navigation. Measure of performance: maritime

transportation capacity meets demand and vessel mishaps remain proportional to number of ship movements.

- 5.3.4.8. DOD, in coordination with DHS and DOS, shall identify those domestic and foreign airports and seaports that are considered strategic junctures for major military deployments and evaluate whether additional risk-based protective measures are needed, within 18 months. Measure of performance: identification of critical air and seaports and evaluation of additional risk-based procedures, completed.

**5.3.5. Determine the spectrum of infrastructure-sustainment activities that the U.S. military and other government entities may be able to support during a pandemic, contingent upon primary mission requirements, and develop mechanisms to activate them.**

- 5.3.5.1. DOT, in coordination with DHS and other ESF #1 support agencies, shall monitor and report the status of the transportation sector, assess impacts, and coordinate Federal and civil transportation services in support of Federal agencies and State, local, and tribal entities (see Chapter 6 — Protecting Human Health, for information on patient movement (ESF #8)). Measure of performance: when ESF #1 is activated, regular reports provided, impacts assessed, and services coordinated as needed.
- 5.3.5.2. DOT, in coordination with DHS and other ESF #1 support agencies, shall coordinate emergency transportation services to support domestic incident management, including transport of Federal emergency teams, equipment, and Federal Incident Response supplies. Measure of performance: all appropriate Federal, State, local, and tribal requests for transportation services provided on time via ESF #1 of the NRP.
- 5.3.5.3. DOT, in coordination with DHS, State, local, and tribal governments, and the private sector, shall monitor system closures, assess effects on the transportation system, and implement contingency plans. Measure of performance: timely reports transmitted to DHS and other appropriate entities, containing relevant, current, and accurate information on the status of the transportation sector and impacts resulting from the pandemic; when appropriate, contingency plans implemented within no more than 24 hours of a report of a transportation sector impact or issue.
- 5.3.5.4. DOT, in support of DHS and in coordination with other ESF #1 support agencies, shall work closely with the private sector and State, local, and tribal entities to restore the transportation system, including decontamination and re-prioritization of essential commodity shipments. Measure of performance: backlogs or shortages of essential commodities and goods quickly eliminated, returning production and consumption to pre-pandemic levels.
- 5.3.5.5. DOD, when directed by Secretary of Defense and in accordance with law, shall monitor and report the status of the military transportation system and those military assets that may be requested to protect the borders, assess impacts (to include operational impacts), and coordinate military services in support of



Federal agencies and State, local, and tribal entities. Measure of performance: when DOD activated, regular reports provided, impacts assessed, and services coordinated as needed.

- 5.3.5.6. DOT and DHS, in coordination with NEC, Treasury, DOC, HHS, DOS, and the interagency modeling group, shall assess the economic, safety, and security related effects of the pandemic on the transportation sector, including movement restrictions, closures, and quarantine, and develop strategies to support long-term recovery of the sector, within 6 months of the end of a pandemic. Measure of performance: economic and other assessments completed and strategies implemented to support long-term recovery of the sector.

*c. Ensuring Effective Risk Communication*

**5.3.6. Ensure that timely, clear, coordinated messages are delivered to the American public from trained spokespersons at all levels of government and assist the governments of affected nations to do the same.**

- 5.3.6.1. DOT and DHS, in coordination with HHS, DOS, and DOC, shall conduct media and stakeholder outreach to restore public confidence in travel. Measure of performance: outreach delivered and traveling public resumes use of the transportation system at or near pre-pandemic levels.
- 5.3.6.2. DHS and DOT, in coordination with DOS, DOD, HHS, USDA, DOI, and State, local, and tribal governments, shall provide the public and business community with relevant travel information, including shipping advisories, restrictions, and potential closing of domestic and international transportation hubs. Measure of performance: timely, consistent, and accurate traveler information provided to the media, public, and business community.

# PANDEMIC INFLUENZA

## WHO Global Pandemic Phases and the Stages for Federal Government Response

| WHO Phases            |                                                                                                                                                                                                                               | Federal Government Response Stages |                                                           |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|-----------------------------------------------------------|
| INTER-PANDEMIC PERIOD |                                                                                                                                                                                                                               |                                    |                                                           |
| 1                     | No new influenza virus subtypes have been detected in humans. An influenza virus subtype that has caused human infection may be present in animals. If present in animals, the risk of human disease is considered to be low. | 0                                  | New domestic animal outbreak in at-risk country           |
| 2                     | No new influenza virus subtypes have been detected in humans. However, a circulating animal influenza virus subtype poses a substantial risk of human disease.                                                                |                                    |                                                           |
| PANDEMIC ALERT PERIOD |                                                                                                                                                                                                                               |                                    |                                                           |
| 3                     | Human infection(s) with a new subtype, but no human-to-human spread, or at most rare instances of spread to a close contact.                                                                                                  | 0                                  | New domestic animal outbreak in at-risk country           |
|                       |                                                                                                                                                                                                                               | 1                                  | Suspected human outbreak overseas                         |
| 4                     | Small cluster(s) with limited human-to-human transmission but spread is highly localized, suggesting that the virus is not well adapted to humans.                                                                            | 2                                  | Confirmed human outbreak overseas                         |
| 5                     | Larger cluster(s) but human-to-human spread still localized, suggesting that the virus is becoming increasingly better adapted to humans, but may not yet be fully transmissible (substantial pandemic risk).                 |                                    |                                                           |
| PANDEMIC PERIOD       |                                                                                                                                                                                                                               |                                    |                                                           |
| 6                     | Pandemic phase: increased and sustained transmission in general population.                                                                                                                                                   | 3                                  | Widespread human outbreaks in multiple locations overseas |
|                       |                                                                                                                                                                                                                               | 4                                  | First human case in North America                         |
|                       |                                                                                                                                                                                                                               | 5                                  | Spread throughout United States                           |
|                       |                                                                                                                                                                                                                               | 6                                  | Recovery and preparation for subsequent waves             |



# PANDEMIC INFLUENZA

## Stages of Federal Government Response



**STAGE 3****Widespread  
Outbreaks Overseas****GOALS**

Delay emergence  
in North America

Ensure earliest  
warning of first case(s)

Prepare domestic containment  
and response mechanisms

**ACTIONS**

Activate domestic emergency  
medical personnel plans

Maintain layered screening  
measures at borders

Deploy pre-pandemic vaccine  
and antiviral stockpiles; divert to  
monovalent vaccine production

Real-time modeling; heighten  
hospital-based surveillance

Prepare to implement surge plans  
at Federal medical facilities

**POLICY DECISIONS**

Prioritize efforts for domestic  
preparedness and response

**STAGE 4****First Human Case  
in North America****GOALS**

Contain first cases in  
North America

Antiviral treatment  
and prophylaxis

Implement national response

**ACTIONS**

Ensure pandemic plans  
activated across all levels

Limit non-essential  
domestic travel

Deploy diagnostic  
reagents for pandemic  
virus to all laboratories

Continue development of  
pandemic vaccine

Antiviral treatment and targeted  
antiviral prophylaxis

**POLICY DECISIONS**

Revision of prioritization  
and allocation scheme for  
pandemic vaccine

**STAGE 5****Spread throughout  
United States****GOALS**

Support community response

Preserve critical infrastructure

Mitigate illness, suffering,  
and death

Mitigate impact to economy  
and society

**ACTIONS**

Maintain overall  
situational awareness

Evaluate epidemiology;  
provide guidance on  
community measures

Deploy vaccine if available;  
prioritization guidance

Sustain critical infrastructure,  
support health and medical  
systems, maintain civil order

Provide guidance on use of  
key commodities

**POLICY DECISIONS**

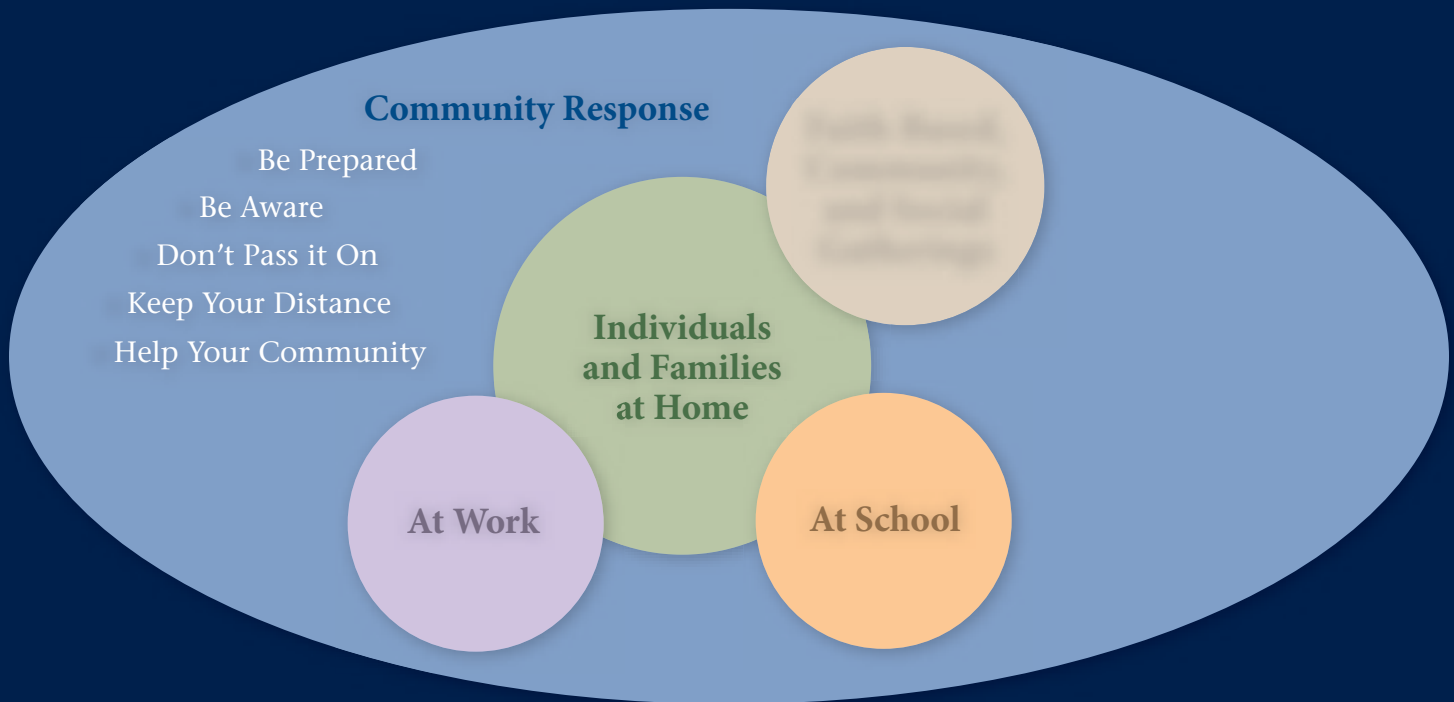
Federal support of critical  
infrastructure and availability of  
key goods and services

Lifting of travel restrictions

**WHO Phase 6  
Pandemic Period**

# PANDEMIC INFLUENZA

## Individual, Family, and Community Response to Pandemic Influenza



| Response            | Individuals and Families                                                                                                                                          | At School                                                                                                                                       | At Work                                                                                                        | Faith-Based, Community, and Social Gatherings                                                                                                 |
|---------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|
| Be Prepared         | Review Individuals and Families Planning Checklist <a href="http://www.pandemicflu.gov">www.pandemicflu.gov</a>                                                   | Review School Planning Checklists <a href="http://www.pandemicflu.gov">www.pandemicflu.gov</a>                                                  | Review Business Planning Checklist <a href="http://www.pandemicflu.gov">www.pandemicflu.gov</a>                | Review Faith-Based and Community Organizations Preparedness Checklist <a href="http://www.pandemicflu.gov">www.pandemicflu.gov</a>            |
| Be Aware            | Identify trusted sources for information; stay informed about availability/use of anti-viral medications/vaccine                                                  | Review school pandemic plan; follow pandemic communication to students, faculty, and families                                                   | Review business pandemic plan; follow pandemic communication to employees and families                         | Stay abreast of community public health guidance on the advisability of large public gatherings and travel                                    |
| Don't Pass it On    | If you are ill--stay home; practice hand hygiene/cough etiquette; model behavior for your children; consider voluntary home quarantine if anyone ill in household | If you are ill--stay home; practice hand hygiene/cough etiquette; ensure sufficient infection control supplies                                  | If you are ill--stay home; practice hand hygiene/cough etiquette; ensure sufficient infection control supplies | If you are ill--stay home; practice hand hygiene/cough etiquette; modify rites and religious practices that might facilitate influenza spread |
| Keep Your Distance  | Avoid crowded social environments; limit non-essential travel                                                                                                     | Prepare for possible school closures; plan home learning activities and exercises; consider childcare needs                                     | Modify face-to-face contact; flexible worksite (telework); flexible work hours (stagger shifts); snow days     | Cancel or modify activities, services, or rituals; follow community health social distancing recommendations                                  |
| Help Your Community | Volunteer with local groups to prepare and assist with emergency response; get involved with your community as it prepares                                        | Contribute to the local health department's operational plan for surge capacity of health care (if schools designated as contingency hospitals) | Identify assets and services your business could contribute to the community response to a pandemic            | Provide social support services and help spread useful information, provide comfort, and encourage calm                                       |

## CHAPTER 6 — PROTECTING HUMAN HEALTH

### Introduction

Protecting human health is the crux of pandemic preparedness, and the goals and pillars of the *National Strategy for Pandemic Influenza (Strategy)* reflect this. If we fail to protect human health, we are likely to fail in our secondary goals of preserving societal function and mitigating the social and economic consequences of a pandemic. Consequently, the components of the Strategy, the elements of this Implementation Plan (Plan), and the projected allocation of resources to preparedness, surveillance, and response activities all reflect the overarching imperative to reduce the morbidity and mortality caused by a pandemic. In order to achieve this objective, we must leverage all instruments of national power and ensure coordinated action by all segments of government and society, while maintaining constitutional government, law and order, and other basic societal functions.

The emergence of an easily transmissible novel strain of influenza into a human population anywhere poses a threat to societies everywhere. Influenza does not respect geographic or political boundaries. When pandemic strains emerge they sweep through communities and nations with frightening velocity. The three pandemics of the 20th century each encircled the globe, sparing few if any communities, within months of their emergence into human populations. The cumulative and concentrated mortality of a pandemic can be appalling. The 1918 pandemic, for example, killed more people in 6 months than acquired immunodeficiency syndrome (AIDS) has killed in the last 25 years and more than were killed in all of World War I. The primary strategy for protecting human health, therefore, must be prevention of emergence of a pandemic strain from animal reservoirs, if possible, or rapid containment of a human outbreak at the source, if emergence does occur. Federal Government efforts to prepare for and to support prevention and containment strategies are described throughout this document.

Protecting human health in the setting of a pandemic will require: (1) effective domestic and international surveillance for, and prompt response to, influenza outbreaks in both humans and animals; (2) improved diagnostic tests; (3) the rapid development, production, and distribution of definitive medical countermeasures (i.e., vaccines); (4) the targeted and effective use of antiviral medications and other potentially scarce medical resources to treat symptomatic individuals; (5) the judicious application of community infection control measures; (6) effective communication of risk reduction strategies to the private sector and to individuals; and (7) the full collaboration of the public and the private sector. A dynamic and resourceful public health and medical response has the potential to save lives by delaying the occurrence of outbreaks, decreasing the proportion of the population who develop influenza or become critically ill, and reducing the burden on critical health care facilities. For such a response to occur, Federal, State, local, and tribal officials must ensure that all stakeholders understand their responsibilities and are adequately prepared to play their part, they must prioritize the use of scarce resources, and they must ensure the continuity of essential government, emergency, and medical services.

Fortunately, we live in an era of great medical and scientific progress. Today we have a better understanding of the influenza virus and the illness that it causes than ever before. Vaccinology is making rapid strides and we are learning more about the use of adjuvants and other dose-sparing strategies. Two new and effective antiviral medications (oseltamivir and zanamivir) have received Food and Drug Administration (FDA) approval in the last 7 years. We understand much more about the transmission dynamics and epidemiology of influenza than we did at the time of the last pandemic, in 1968. We have better international and domestic disease surveillance systems and we have developed a national network

of diagnostic laboratories incorporating standardized reagents and protocols. Since September 11, 2001, we have made significant investments in all aspects of public health emergency preparedness. We are, in short, better prepared than ever to meet the immense challenge posed by a pandemic.

But the challenge will be formidable. We do not understand why some influenza viruses are efficiently transmitted and some are not. In the event of a pandemic, we will have to overcome severe shortfalls in surge capacity in our health care facilities. Our current vaccine production capabilities cannot keep pace with an evolving pandemic. We lack adequate stockpiles of antiviral medications and plans to distribute the supplies we have. Most surveillance systems do not operate in real time. We cannot quantify the value of many infection control strategies and do not know the optimal timing for or sequencing of those that would affect entire communities. Finally, and perhaps most importantly, members of the public may not appreciate the importance of the care they will provide to ill family members, the degree to which they can modify their risk of becoming ill, nor the extent to which their collective actions will shape the course of a pandemic.

## Key Considerations

The overarching strategic goals of the *Strategy* are to: (1) stop, slow, or limit the spread of disease; (2) mitigate disease, suffering, and death; and (3) sustain infrastructure and mitigate impact to the economy and the functioning of society. These goals are not sequential but mutually supportive. The objective of the *Strategy* is to accomplish all three goals, to whatever extent possible, at all times during a pandemic.

## Epidemiology

The transmission of a communicable agent between individuals is a chance event, the probability of which varies according to the nature and intimacy of their interactions. Epidemics occur when, on average, an infected individual transmits infection to more than one other person ( $R_0$ , or reproductive rate,  $>1$ ). Conversely, and critically, outbreaks of infectious disease will diminish and ultimately terminate when, on average, an infected individual transmits infection to less than one other person (reproductive rate less than one). *The key to stopping an epidemic is to bring the reproductive rate below 1 and keep it there through whatever means, or combination of means, feasible.* These means can include the administration of effective vaccines or antiviral prophylaxis, the identification and isolation of infected individuals and quarantine of their contacts, and the implementation of appropriate infection control and social distancing measures.

The velocity of an epidemic — the speed with which an epidemic spreads through a community — is a function of the basic reproductive rate for the disease in question and how long it takes for infected individuals to infect others (generation time, or  $T_g$ ). Influenza is moderately infectious but has a very short generation time. Recent estimates have suggested that while the reproductive rate for most strains of influenza is less than 2, the generation time may be as little as 2.6 days. These parameters predict that in the absence of disease containment measures the number of cases of epidemic influenza will double about every 3 days. It is important to note that the magnitude of the reproductive rate determines the intensity of measures required to halt transmission, while the components of the generation time — that is, the duration of the latent and infectious periods — determine how and when these measures must be applied.

Patients with influenza typically become infectious after about 1 to 1.5 days and prior to becoming symptomatic. At about 2 days, most infected persons will develop symptoms of illness, the spectrum and severity of which may vary considerably. Understanding the natural history of influenza makes it possible

to assess potential response measures and determine the factors critical for their success. Given that 2 days will elapse between infection and illness in most cases, for example, a significant percentage of infected persons who travel internationally to the United States and are asymptomatic when boarding a flight will still be well upon arrival and will not be detected by screening at the border.

### **Pivotal Importance of Initial Conditions**

While we cannot predict the severity of a pandemic before it begins, the initial analysis of the characteristics of the virus and its epidemiology will tell us much about the way in which the pandemic will unfold. The cardinal determinants of the public health response to a pandemic will be its severity, as defined by the ability of the pandemic virus to cause severe morbidity and mortality, especially in otherwise low-risk populations, and the availability and effectiveness of vaccine and antiviral medications.<sup>15</sup> Decisions about the prioritization and distribution of medical countermeasures; the content of risk communication campaigns; the application of community infection control measures; and whether and when to make adjustments in the delivery of care commensurate with available resources are interrelated and all fundamentally determined by these factors, which will be known from the beginning of an outbreak. These are the critical triggers that will dictate the actions of public health authorities.

Severe pandemics, for example, pose the greatest threat to critical infrastructure and national security. Groups receiving priority access to medical countermeasures during a severe pandemic will reflect the need to maintain infrastructure and security functions. When vaccine and antiviral drug supplies are very limited, targeting necessarily will be narrower and the importance of community infection control measures will be greater. An inadequate supply of countermeasures in the setting of a severe pandemic would also be an indication to authorities to expand surge capacity and prepare to alter standards of care by expanding staff, extending the defined roles of providers, and establishing infirmaries. Public messaging to health care professionals, other stakeholders, and the general public would seek to prepare them for a severe pandemic and the shortage of medical countermeasures. It would not be necessary to wait for numbers of cases to rise exponentially.

Greater vaccine and antiviral drug supply, on the other hand, would permit more flexibility in the strategies and objectives for the use of medical countermeasures. Preservation of critical infrastructure and security functions would still be crucial, but consideration might also be given to efforts to decrease transmission of infection in communities through the early immunization of children or by providing post-exposure prophylaxis to household contacts of ill persons. Anticipating a pandemic caused by a highly pathogenic virus, authorities would still move to expand surge capacity and prepare to change the way care is delivered by expanding staff, extending the defined roles of providers, and establishing infirmaries. Public messaging would be tailored accordingly.

In a less severe pandemic, where infrastructure and security concerns are not as significant, efforts could be focused on protecting those at high risk for severe disease and death from the beginning, especially if supplies of medical countermeasures are inadequate. Public health authorities might recommend home care, with or without isolation, for the great majority of patients and the costs and benefits of community infection control measures would be calculated differently.

<sup>15</sup> It is important to emphasize that the severity of a pandemic is a function not of the attack rate or transmissibility of the virus, both of which appear to be relatively constant between pandemics, but of its ability to produce severe illness or death. The severity of illness caused by a strain of influenza with pandemic potential will be quickly apparent, although continued monitoring and analysis will be necessary to refine initial assessments.



The value of a decision framework based on pandemic severity and the supply of vaccines and antiviral medications is that such a framework facilitates decisive and concrete pre-pandemic planning and allows the construction, in advance, of response algorithms and decision trees. It is important to caveat these observations by noting that since antiviral resistance can develop over time and the virulence of circulating strains may change as the virus adapts to its human hosts, ongoing monitoring for antiviral resistance and geographically circumscribed or more global changes in vaccine effectiveness or viral pathogenicity during a pandemic will be essential. Strategies for use of vaccine and antiviral medications that are in short supply may shift in response to such observations or as the supply of countermeasures changes over time.

## **Maintaining Situational Awareness**

### *Surveillance*

The goal of influenza surveillance is to track novel influenza subtypes and detect clusters of severe human infection heralding the emergence of strains with pandemic potential, so as to facilitate early and aggressive attempts at containment. International surveillance programs and goals are described in Chapter 4 - International Efforts. Domestic surveillance goals include detection of initial U.S. cases if the pandemic begins abroad, defining its spread, elucidating health impacts and high-risk groups, and monitoring characteristics of the virus, including antigenic and genetic changes, and changes in antiviral resistance patterns.

The Federal Government collects outpatient, hospital, and mortality surveillance data through a variety of systems and networks, and in recent years has improved its capability to aggregate and analyze data in real time. Unfortunately, current systems do not provide sufficient depth and coverage to guide all elements of the national response, and a great deal of analysis and time is required to assess the consequences of seasonal influenza outbreaks and the effectiveness of the annual vaccine. To remedy this shortcoming, and to enhance their own situational awareness, State and local public health departments should make it a priority to establish or enhance influenza surveillance systems within their jurisdictions. To improve national surveillance capabilities, the National Biosurveillance Integration System (NBIS) has been established to provide an all-source biosurveillance common operating picture to improve early-warning capabilities and facilitate national response activities through better situational awareness.

In the event of a pandemic, States should be prepared to increase diagnostic testing for influenza as well as the frequency of reporting to the Centers for Disease Control and Prevention (CDC). Early detection of pandemic virus at a local level requires the collection and testing of appropriate specimens as recommended. The most intense testing will be necessary during the early stages of a pandemic, when detecting the introduction of the virus into a State or community is the primary goal.

### *Response*

Maintaining situational awareness during a pandemic will be extremely difficult. In addition to the surveillance and disease reporting activities described above, Federal, State, and local authorities will also be called upon to collect, analyze, integrate, and report information about the status of their hospitals and health care systems, critical infrastructure, and materiel requirements, and they will be called upon to supply such information at a time when their capabilities may be eroded by significant absenteeism.

Hospital and health care resource tracking can and should be performed in real time. The identification of stress points and focal insufficiencies in real time will permit the burden of patient care to be distrib-

uted across health care systems more equitably, preserving core functionalities despite significant and even extreme surges in demand. Additionally, the early recognition of increased systemic loads could serve as a trigger to public health officials to implement or promote more stringent disease containment measures and to make adjustments in the delivery of care commensurate with available resources.

Implementing disease containment and infection control measures is likely to impose significant costs on affected communities. Determining the optimal timing and thresholds for interventions with significant associated costs will be difficult in the absence of quantitative data about their effectiveness and the benefits they will confer. Insights into the biology and patterns of transmission of pandemic influenza, as well as the efficacy of various disease containment strategies, will evolve in real time and should be tractable to analysis and modeling.

### **Role of Rapid and Reliable Diagnostic Tests**

During periods of heightened surveillance for the emergence of novel influenza strains and early in a pandemic, when disease is localized in one or several countries, both clinical and epidemiological (e.g., exposure) characteristics are important for surveillance and case detection. As the pandemic begins to spread, rapid diagnostic tests may be widely used to distinguish influenza A from other respiratory illnesses. Once pandemic disease is widespread, cases will be identified primarily by clinical presentation. Historically, most patients with pandemic influenza have presented with signs and symptoms similar to those of seasonal influenza, although in some the presentation is more fulminant and progresses very rapidly.

Rapid diagnostic tests for influenza are screening tests for influenza virus infection that provide results within 60 minutes and can be used for individuals or groups. Diagnostic tests will be most critical in the early phases of a pandemic, when identification of the first cases in a locality is important, and they may also be useful as the epidemic declines and pandemic disease becomes less prevalent. Depending on their sensitivity and specificity, such tests might also facilitate screening of travelers at ports of entry or prior to boarding inbound flights. At present, widely available rapid diagnostic tests and testing protocols do not distinguish between specific subtypes and strains of influenza and, because of their suboptimal sensitivity and specificity, cannot even definitively distinguish between influenza and other causes of similar illness. Because the available diagnostic tests have differing sensitivities, specificities, and technical requirements, they may find use in different settings and for different purposes during a pandemic.

New technologies and new approaches are driving down costs and improving the specificity and sensitivity of rapid diagnostic tests to the point that subtype- and strain-specific tests may be available for large-scale screening within the next couple of years. If these tests can be packaged in a way that facilitates their use in non-clinical settings, their potential to facilitate disease containment efforts will be even greater, by allowing more effective screening of travelers (and thus the more targeted application of movement restrictions) or even by identifying patients before they become symptomatic or infectious. The Federal Government will continue to support research in this area, in an effort to promote such advances.

In the interim, existing diagnostic technologies must be used to greatest effect to rapidly screen individuals infected with pandemic influenza. To this end, the Department of Health and Human Services (HHS), the Department of Agriculture (USDA), the Department of Energy (DOE), the Environmental Protection Agency (EPA), the Department of Defense (DOD), the Federal Bureau of Investigation (FBI), and the Department of Homeland Security (DHS) participate, with State and local public health laboratories, in the Laboratory Response Network (LRN), the member laboratories of which have adopted



uniform diagnostic standards, protocols, and reagents, and can perform subtype- and strain-specific confirmation testing for influenza. HHS and the private sector have also developed high-throughput rapid diagnostic kits that will undergo field testing by U.S. and Southeast Asian scientists and public health officials to ascertain the utility and robustness of these products.

### **Countermeasure Production, Prioritization, Distribution, and Security**

The optimal way to control the spread of a pandemic and reduce its associated morbidity and mortality is through the use of vaccines. Broadly speaking, vaccines may be divided into those that are developed against strains of animal influenza viruses that have caused isolated infections in humans, which may be regarded as “pre-pandemic” vaccines, and those that are developed against strains that have evolved the capacity for sustained and efficient human-to-human transmission (“pandemic” vaccines). Because emergence in human populations necessarily reflects genetic changes within the pandemic virus, pre-pandemic vaccines may be a good or poor match for — and offer greater or lesser protection against — the pandemic strain that ultimately emerges.

Current FDA-licensed inactivated influenza vaccines are based on technologies developed more than 30 years ago. Scientists first select the three virus strains that they expect to circulate in the United States during the following season. These strains are then adapted to grow in fertilized chicken eggs and manufacturers inject each adapted virus strain separately into millions of eggs, which are subsequently incubated to produce influenza virus. Large batches of these eggs are harvested and the viral particles that are obtained are inactivated, chemically disrupted, and blended into a single vaccine product that includes all three influenza virus strains. A single dose of the trivalent vaccine contains 15 ug of hemagglutinin for each of the three antigenic components. The total dose (45 ug) is approximately the amount of purified virus obtained from the allantoic fluid of one egg. Current manufacturing processes thus require manufacturers to procure one fertilized chicken egg for every dose of vaccine produced and are dependent on the timely availability of vaccine seed strains.

Antiviral medications can be used for treatment or prophylaxis of people exposed to influenza. Currently only two classes of medication — the neuraminidase inhibitors and the adamantanes — demonstrate efficacy against circulating influenza viruses. Both classes of medication are most effective if administered in the earliest stages of infection. Adamantane resistance emerges fairly quickly (adamantane-resistant H5N1 influenza already circulates, for example) and does not appear to affect viral fitness, in terms of the transmissibility of the virus or its ability to produce illness. Resistance to oseltamivir, the oral neuraminidase inhibitor, emerges more slowly but has been associated with treatment failure in patients with H5N1 influenza. Resistance to zanamivir, the inhaled neuraminidase inhibitor, has not been documented in immunocompetent hosts, but its efficacy in treating patients with H5N1 or other subtypes and strains with pandemic potential requires further assessment.

#### *Production*

The Federal Government has established two primary vaccine goals: (1) establishment and maintenance of stockpiles of pre-pandemic vaccine adequate to immunize 20 million persons against influenza strains that present a pandemic threat; and (2) expansion of domestic influenza vaccine manufacturing surge capacity for the production of pandemic vaccines for the entire domestic population within 6 months of a pandemic declaration.

While progress can be made toward the first goal with current egg-based manufacturing methods, the existing domestic influenza vaccine manufacturing base lacks sufficient surge capacity to meet the

second. Moreover, since populations have no baseline immunity to strains of influenza with pandemic potential, it is highly probable that more vaccine antigen will be required per person to induce protective immunity. The amount of vaccine antigen that is currently manufactured is matched to the usual requirements for seasonal influenza vaccine, and not the requirements for a pandemic vaccine, which may require significantly more hemagglutinin per person than a seasonal vaccine to induce an effective immune response. Furthermore, in the event of a pandemic it is likely that bulk influenza vaccine manufactured outside the United States (and accounting for about 40 percent of annual domestic supply) will be unavailable. Thus, the measures taken by the Federal Government over the past several years to ensure a secure egg supply and support the expansion and diversification of influenza vaccine manufacturing capacity will require significant enhancement and acceleration.

The Federal Government has adopted a three-pronged strategy to secure the required surge capacity for pre-pandemic and pandemic vaccines. Current initiatives fall broadly under the categories of advanced vaccine development, establishment, and expansion of new U.S. vaccine manufacturing facilities, and vaccine acquisition. In keeping with our goal of developing a rapid response vaccine manufacturing capability, we will support the advanced development of cell-based influenza vaccine candidates. The Federal Government will also support the renovation of existing U.S. manufacturing facilities that produce other FDA-licensed cell-based vaccines or biologics as well as the establishment of new domestic cell-based influenza vaccine manufacturing facilities.<sup>16</sup> To accommodate pre-pandemic vaccine needs without disturbing seasonal influenza vaccine manufacturing campaigns, the Federal Government will continue through 2008 to procure H5N1 vaccine from manufacturers of U.S.-licensed influenza vaccines. With these and other initiatives, the pandemic vaccine capacity goal for the United States may be within reach by the end of 2010.

Improvements in vaccine technology may alleviate some vaccine capacity concerns. Dose-sparing strategies for influenza vaccines that are currently under evaluation may reduce the requirement for vaccine antigen per dose and/or allow for effective immunization with a single shot. In the future, broad-spectrum influenza vaccines may supplement seasonal and pandemic influenza vaccines to provide broader virus specificity and longer persistence of enhanced immunity, especially in the populations most vulnerable to influenza — children, the elderly, and the chronically ill.

The Federal Government has established two primary goals for stockpiling existing antiviral medications: (1) establishment and maintenance of stockpiles adequate to treat 75 million persons, divided between Federal and State stockpiles; and (2) establishment and maintenance of a Federal stockpile of 6 million treatment courses reserved for containment efforts. In an effort to expand the medical armamentarium, the Federal Government is also supporting research projects to optimize dosing strategies for existing antiviral medications, identify novel drug targets, and develop compounds that inhibit viral entry, replication, and maturation.

<sup>16</sup> Cell-based manufacturing methods use mammalian cells to grow the influenza viruses used in the vaccine and offer a number of advantages. Vaccine manufacturers can bypass the step needed to adapt the virus strains to grow in eggs. Cells may be frozen in advance and large volumes grown quickly. U.S. licensure and manufacture of influenza vaccines produced in cell culture also will provide security against risks associated with egg-based production, such as shortages and the potential for egg supplies to be contaminated by various poultry-based diseases. Finally, the new cell-based influenza vaccines will provide an option for people who are allergic to eggs and therefore unable to receive the currently

licensed vaccines. It should be noted that certain issues must be addressed by extensive testing and characterization prior to the banking and use of mammalian cells for vaccine production. For example, such cells may be at risk of contamination with various disease-causing organisms affecting the animals from which the cells or cell-growth media components were derived, and there may be tumorigenicity concerns with cells that may be useful for high-yield manufacturing.

*Prioritization*

The Federal Government is developing guidelines to assist State and local governments and the private sector in defining groups that should receive priority access to scarce medical countermeasures. Priority recommendations will reflect the pandemic response goals of limiting mortality and severe morbidity; maintaining critical infrastructure and societal function; diminishing economic impacts; and maintaining national security. Limiting transmission also may be an objective. Antiviral prophylaxis of household contacts of infected individuals and vaccination of children may decrease disease spread in affected communities but would require large quantities of drug and vaccine. If supplies and public health resources were sufficient, these strategies might be pursued in certain settings.

Priorities for vaccine and antiviral drug use will vary based on pandemic severity as well as the vaccine and drug supply. In settings of very limited vaccine and drug supply, narrow targeting and efficient use are required. Vaccine may be reserved for critical personnel, while antiviral medications are reserved for symptomatic individuals who are at high risk of serious complications or death. With greater availability, it may be feasible to expand priority groups and implement strategies to limit disease transmission. Recognizing that no single priority list is appropriate for all scenarios, Federal guidance will be developed for multiple contingencies.

The use of pre-pandemic vaccine will be targeted to maintain critical societal functions through the protection of critical infrastructure personnel and to protect those who are at greater risk of early exposure and infection during a pandemic, such as health care providers or first responders. Pre-pandemic vaccination objectives may include primary immunization if the match between the pre-pandemic vaccine and the circulating virus is close, or priming the immune system to respond more rapidly and robustly to an initial dose of pandemic vaccine, when it becomes available, if the match is suboptimal.

Recommendations put forward by the Advisory Committee on Immunization Practices and the National Vaccine Advisory Committee are included in the *HHS Pandemic Influenza Plan* and provide initial guidance to Federal, State, local, and tribal partners regarding many of the potential target groups being considered.

*Distribution*

When sustained and efficient human-to-human transmission of a potential pandemic influenza strain is documented anywhere in the world, the Federal Government will develop and distribute recommendations on target groups for vaccine and antiviral drugs. These recommendations will reflect data from the pandemic and available supplies of medical countermeasures in light of the considerations outlined above. These recommendations will be provided to Federal health care providers and State, local, and tribal authorities.

A treatment course of oseltamivir for adults and adolescents ages 13 and above is 1 capsule taken twice daily for 5 days, or 10 capsules. A typical prophylaxis course for adults and adolescents is one capsule taken once daily for at least 10 days, although oseltamivir has been shown to be safe and effective when taken for up to 6 weeks. Because prophylaxis requires significantly more medication, results in the administration of a scarce medical resource to people who might not have become sick in any case, and only reduces risk during the period when the medication is being taken, current plans propose using antiviral medication stockpiles only for treatment once a pandemic is underway. Prophylactic use of antiviral medications will be reserved for initial containment efforts and other highly select circumstances.

Given the highly distributed nature of a pandemic, the need to deliver antiviral prophylaxis within 2 days of exposure or to provide therapy to infected patients within 2 days of the onset of symptoms presents significant unresolved logistical challenges. It will be necessary to develop and exercise pandemic influenza countermeasure distribution plans in each of the States and territories and public-private partnerships supporting the seamless, efficient, and timely distribution of these countermeasures may also be required.

### *Security*

It is conceivable that criminal elements may try to take advantage of medical countermeasure scarcity and citizens' fears regarding a pandemic by producing and distributing counterfeit vaccines and antiviral medications. The Federal Government will aggressively monitor efforts to produce and distribute counterfeit drugs, both domestically and internationally, and ensure that existing laws are vigorously enforced in order to deter such conduct, protect the integrity of our drug supply, and maintain public confidence.

### **Reducing Disease Transmission and Rates of Illness**

While preventing a pandemic after person-to-person transmission becomes well established may be impossible, the systematic application of disease containment measures can significantly reduce disease transmission rates with concomitant reductions in the intensity and velocity of any pandemics that do occur. The goals of disease containment after a pandemic is underway are to delay the spread of disease and the occurrence of outbreaks in U.S. communities, to decrease the clinical attack rate in affected communities, and to distribute the number of cases that do occur over a longer interval, so as to minimize social and economic disruption and to minimize, so far as possible, hospitalization and death. Investigation of early local outbreaks of pandemic influenza will provide helpful clinical and epidemiological information and support real-time modeling of pandemic response measures.

The primary strategies for preventing pandemic influenza are the same as those for seasonal influenza: vaccination; early detection and treatment with antiviral medications; and the use of infection control measures to prevent transmission. However, when a pandemic begins, a vaccine might not be widely available, and the supply of antiviral drugs may be limited. The ability to limit transmission and delay the spread of the pandemic will therefore rely primarily on the appropriate and thorough application of infection control measures in health care facilities, the workplace, the community, and for individuals at home. CDC recommendations in this regard are described at length in Supplement 4 of the *HHS Pandemic Influenza Plan*.

In the initial stages of a domestic outbreak, it might be feasible to perform case tracking and contact tracing, with isolation of individuals with known pandemic influenza and voluntary quarantine of their close contacts. Antiviral post-exposure prophylaxis targeted at contacts of the first cases identified in the United States may slow the spread of the pandemic. Quarantine of case contacts has played an important role in the management of outbreaks of other diseases transmitted by large-particle droplets, but its role in containing influenza has not been fully defined.

Depending on the severity of a pandemic and its anticipated effects on health care systems and the functioning of critical infrastructure, communities may recommend or implement general measures to promote social distancing and the disaggregation of disease transmission networks. As a general rule, the value of such measures will be greatest if the interventions are implemented early in the course of a community outbreak and sustained until definitive countermeasures are available. In the case of a pandemic, where it may not be possible to delay the spread of disease indefinitely, the goal of such meas-

ures will be to decrease the clinical attack rate and to distribute the number of cases that do occur over a longer interval, so as to minimize social and economic disruption.

Some social distancing measures, such as the recommendation to maintain one-yard spatial separation between individuals or the recommendation to businesses to conduct meetings by teleconference, will be sustainable indefinitely at comparatively minimal cost, whereas others (e.g., implementation of “snow day” restrictions) are associated with substantial costs and can be sustained only for limited periods. Low-cost or sustainable social distancing measures should be introduced immediately after a community outbreak begins, while the more costly and non-sustainable measures should be reserved for situations in which the need for disease containment is critical. Decisions as to how and when to implement such social distancing measures will be made on a community-by-community basis, with the Federal Government providing technical support and guidance to local officials.

The clinical attack rates for seasonal and pandemic influenza are highest among children. Closure of schools and targeted vaccination of children have demonstrated efficacy in diminishing community influenza rates. Modeling supports school closure as an effective means of reducing overall attack rates within communities and suggests that the value of this intervention is maximized if school closure occurs early in the course of a community outbreak. Cancellation of non-essential public gatherings, restrictions on long-distance travel, and social distancing within the workplace could also potentially decrease rates of influenza transmission, but the real-world effectiveness of these interventions has not been quantified. Measures to be considered within schools and in the workplace are described in Chapter 9.

“Snow day” restrictions — the recommendation or mandate by authorities that individuals and families limit social contacts by remaining within their households — should reduce community transmission rates and would afford protection to households where infection has not yet occurred. How long and how effectively snow day restrictions can be maintained has not been determined and thus the value of such restrictions has not been quantified. For maximum effectiveness and to the extent possible, snow day restrictions should be maintained for at least two incubation periods, as defined by epidemiological analysis of the circulating pandemic strain. In the absence of definitive countermeasures (i.e., an effective vaccine), snow day restrictions will serve to disrupt but not stop community transmission of influenza. The uses of snow day restrictions during a pandemic will vary. They might be employed to decompress health care facilities by temporarily reducing the rate of new infections within an affected community. The optimal timing for the implementation of snow day restrictions has not been determined but should be tractable to modeling. The economic impacts of snow day restrictions could be quite large and should be weighed against the likely health benefits.

### **Geographic Quarantine (*Cordon Sanitaire*)**

Geographic quarantine is the isolation, by force if necessary, of localities with documented disease transmission from localities still free of infection. It has been used intermittently throughout history in efforts to contain serious epidemics and must be differentiated from the quarantine of case contacts, where exposure to an infectious agent but not infection per se has been confirmed. Geographic quarantine results in the detention, within an epidemic zone, of persons who may or may not have been exposed to the pathogen in question. Some nations, notably Australia in the fall of 1918, have imposed reverse geographic quarantines, in an effort to keep epidemic disease out. The value of efforts to impose modified forms of reverse geographic quarantine is discussed at greater length in Chapter 5. In summary, even if such efforts prove unsuccessful, delaying the spread of the disease could provide the Federal Government with valuable time to activate the domestic response.



Once influenza transmission has occurred in multiple discrete locations, and it is clear that containment efforts have failed, the value of conventional geographic quarantine as a disease containment measure in any particular locality will be profoundly limited. Whether geographic quarantine should play a role in efforts to contain an outbreak of influenza with pandemic potential at its source will depend on the area and population affected, whether the implementation of a *cordon sanitaire* is feasible, the likelihood of success of other public health interventions, the ability of authorities to provide for the needs of the quarantined population, and in all likelihood geopolitical considerations that are beyond the scope of this chapter. The implementation of conventional geographic quarantine imposes significant opportunity costs and may result in the diversion of significant resources and assets that might be used to better effect supporting less draconian disease containment measures.

Quarantine at the level of families and individuals is a legitimate public health intervention that figured prominently in the public health response to severe acute respiratory syndrome (SARS). It is important to underscore that the value of individual quarantine as a public health intervention is determined by the biology of the agent against which it is directed. Because influenza infection can be transmitted by persons who are not ill, and because viral shedding occurs prior to the onset of clinical illness, isolation of ill persons or exclusion from work of those who are ill will reduce but not prevent transmission in public settings. Because of influenza's short generation period, isolation and quarantine must be implemented very quickly to have an impact and will not be as effective as for a disease like SARS or smallpox where the generation time is longer and asymptomatic shedding of virus does not appear to be significant. Nevertheless, the value of isolating patients with pandemic influenza and quarantining their contacts is clearly supported by recent modeling efforts.

### Expanding Medical Surge Capacity

While a pandemic may strain hundreds of communities simultaneously, each community will experience the pandemic as a local event. In the best of circumstances, patients and health care resources are not easily redistributed; in a pandemic, conditions would make the sharing of resources and burdens even more difficult. The Federal Government will provide medical countermeasures, resources, and personnel, if available, in support of communities experiencing pandemic influenza, but communities should anticipate that in the event of multiple simultaneous outbreaks, the Federal Government may not possess sufficient medical resources or personnel to augment local capabilities. The development of medical and public health mutual aid arrangements through the Emergency Management Assistance Compact (EMAC) and other mechanisms is encouraged, but States and localities should anticipate that all sources of external aid may be compromised during a pandemic.

### Personnel

During a pandemic, the number of persons seeking medical care is expected to increase significantly and overcrowding may lead hospital and other health care institutions to adjust clinical care algorithms in order to optimize the allocation of scarce resources. Since most health professionals are already geographically dispersed, local and State governments are in a position to take primary responsibility for identifying, registering, and coordinating volunteer medical and health care personnel within their jurisdictions to respond to any surge in demand for health care. HHS has partnered with States and localities through the Medical Reserve Corps and the Emergency System for the Advanced Registration of Volunteer Health Professionals (ESAR-VHP) Programs to develop locally sponsored emergency response teams and state-based volunteer registries to recruit, credential, and mobilize health care personnel in the event of a large scale medical emergency.

*Medical Standards of Care*

If a pandemic overwhelms the health and medical capacity of a community, it will be impossible to provide the level of medical care that would be expected under pre-pandemic circumstances. It may be necessary because of hospital overcrowding to establish pre-hospital facilities and alternate-care sites to provide supplemental capacity. In some circumstances, it may be necessary to apply triage principles in the hospital to regulate which patients gain access to intensive care units (ICUs) and ventilators, and it is likely that vaccine, pharmaceuticals, and other medical materiel will also be rationed. Non-clinical personnel and family members may be asked to assist with administrative and environmental tasks, while qualified clinicians may be asked to perform unfamiliar functions such as staffing temporary medical care facilities, visiting patients in their homes, or providing medical advice via on-line or hot-line connections.

The terms ‘altered’ and ‘degraded’ standards of care have often been applied to such situations in both government documents and the medical literature. The legal and ethical ‘standard of care,’ however, is what is reasonably expected of medical systems and providers and is determined by extant circumstances. Relevant conditions include the availability of hospital, ICU, or specialty care beds; medical equipment and materiel; and personnel who are trained and qualified to provide care. As in all situations involving the allocation of scarce medical resources, the standard of care will be met if resources are fairly distributed and are utilized to achieve the greatest benefit. In a pandemic, hospital and ICU beds, ventilators, and other medical services may be rationed. As in other situations of scarce medical resources, preference will be given to those whose medical condition suggests that they will obtain greatest benefit from them. Such rationing differs from approaches to care in which resources are provided on a first-come, first-served basis or to patients with the most severe illnesses or injuries.

Given the strain that a pandemic would place on a community’s medical system, it will be necessary for hospitals, medical providers, and oversight agencies to maximize hospital bed surge capacity, and triage and treat patients in a manner that affords each the best chance of survival and recovery within the limits of available resources. In addition, the public must be informed regarding when, how, and where to obtain medical care. In all cases, the goal should be to provide care and allocate scarce equipment, supplies, and personnel in a way that saves the largest number of lives. Planning should therefore include thresholds for altering triage algorithms and otherwise optimizing the allocation of scarce resources. Where prospective and mature data are available, changes in clinical care algorithms should be evidence-based.

In planning for a prolonged mass casualty event, it must be recognized that persons with unrelated medical conditions will continue to require emergency, acute, and chronic care. It is important to keep the health care system functioning and to deliver the best care possible to preserve as many lives as possible. Planning a health and medical response to a mass casualty event must be comprehensive, community-based, and coordinated at the regional level. In making adjustments in the delivery of care because of constrained resources, individual autonomy, privacy, and dignity should be protected to the extent possible and reasonable under the circumstances. Finally, clear communication with the public is essential before, during, and after a mass casualty event such as a pandemic.

*Availability of Medical Materiel*

Health care facilities typically maintain limited inventories of supplies on-site and depend on just-in-time restocking programs. Replenishment of critical inventories is thus dependent upon an intact supply chain from manufacturing and distribution to transportation and receiving. During a pandemic there

would be an increased demand for both consumable and durable resources. Examples of critical supplies are listed in Supplement 3 to the *HHS Pandemic Influenza Plan*. Competition for these resources at a time of increased demand could result in critical shortages.

Manufacturers and suppliers are likely to report inventory shortages because of the massive simultaneity of need and supply chains may also be disrupted by the effects of a pandemic on critical personnel. Medical facilities should make provision for these considerations in their planning efforts and consider stockpiling critical medical materiel individually or collaborating with other facilities to develop local or regional stockpiles maintained under vendor managed inventory systems.

### *Facilities*

Health care facilities will face increased demand for isolation wards, intensive care unit beds, and ventilators. Historical comparisons and recent severe seasonal influenza epidemics suggest that U.S. health care facilities would be overwhelmed with influenza patients during a pandemic. Extrapolating from the 1918 pandemic, a severe pandemic could result at its peak in the need for significantly more hospital and intensive care unit beds than the U.S. health care system currently supports.

Because of the intense but transient demand for clinical care areas, and because cohorting of patients with pandemic influenza in common treatment areas is an acceptable response to hospital overcrowding, establishing infirmaries in armories or other facilities of opportunity to supplement existing health care facilities is a reasonable consideration for those not critically ill. Suitable spaces can be identified in the pre-pandemic phase, medical materiel and supplies can be stockpiled prospectively, and actions to stand up the infirmary commenced in the early stages of an outbreak. The Federal Government has assembled a limited number of Federal Medical Stations (FMSs), which are scalable, modular, 250-bed deployable caches that require 40,000 square feet of enclosed space and an enabling environment (i.e., loading docks, electrical power source systems, climate control, communications, information technology support) and are configured to provide basic but essential medical care.<sup>17</sup>

### *Psychosocial Concerns*

During a pandemic, psychosocial issues may play significantly contribute to, or hinder, the effectiveness of the response. Public anxiety and subjective perception of risk during the initial phases will impact the degree of medical surge; overall compliance with quarantine, snow days, and other control procedures; and participation of the workforce, including health care workers, in response efforts. In later stages of the epidemic, other psychosocial factors may also emerge. During the 1918-1919 “Spanish flu,” for example, people experienced significant distress due to loss of family members and anxiety about work, food, transportation, and basic infrastructure, while the SARS outbreak in 2003 led to psychological distress for health care workers and the general public because of social isolation, stigmatization of groups perceived to be high risk, and general fears about safety and health. While most people are resilient and will need minimal psychological support to cope with catastrophic events such as an influenza pandemic, it is imperative that planning for behavioral health reactions be undertaken to support affected populations and possibly reduce the occurrence of long-term psychological distress. Such planning should involve efforts to recruit, credential, and mobilize mental health and substance abuse personnel (as part of personnel efforts discussed above), along with the development of materials on psychological self-care and related topics, including a plan for dissemination of such materials.

<sup>17</sup> Staffing for FMS units is not provided automatically but must be drawn from available Federal, State, or local medical personnel.



*Emergency Medical Services*

Emergency Medical Services (EMS) provide critical pre-hospital care and transportation and the individuals engaged in these services are among the high priority groups considered for vaccination. However, when a pandemic begins, a vaccine may not be widely available, and the supply of antiviral drugs may be limited. Illness and absenteeism may adversely affect these services and local governments and hospitals may need to explore alternative methods of transporting patients.

Pre-hospital EMS transportation capability will play a critical role in responding to requests for assistance, providing treatment, and in triaging patients. 9-1-1 call centers/public safety answering points (PSAPs) will experience a significant surge in calls and will determine how and when EMS units are dispatched. Coordination and communication between public health, PSAPs, EMS, and hospital officials will be necessary to ensure optimal patient care as hospital bed availability and pre-hospital resources are strained. Planners should consider modifying PSAP call-taker and dispatch protocols and developing pandemic-specific pre-hospital triage and treatment protocols. A robust statewide or regional system for monitoring PSAP medical calls, EMS responses and transports, and hospital bed availability will be critical for tracking and responding to a pandemic.

Persons with emergency medical licensure not engaged in transporting patients could potentially provide support to personnel working in hospitals and infirmaries and could, with additional education, training and legal authority, broaden their scopes of practice during the emergency and, for instance, administer vaccinations to the public or other emergency support personnel.

*Home-based Care*

Given that most persons with pandemic influenza will experience typical influenza symptoms, most persons who seek care can be managed appropriately by outpatient providers using a home-based approach. Appropriate management of outpatient pandemic influenza cases may reduce the risk of progression to severe disease and thereby reduce demand for inpatient care. A system of effective home-based care would decrease the burden on health care providers and hospitals and lessen exposure of uninfected persons to persons with influenza. Telephone call centers should be established or augmented within affected communities to provide advice on whether to stay home or to seek care. Home health care providers and organizations can provide follow-up for those managed at home, decreasing potential exposure of the public to persons who are ill and may transmit infection.

*Fatality Management*

Given the anticipated increase in the number of deaths associated with an influenza pandemic, hospitals and health care facilities working with State, local, or tribal health officials and medical examiners should assess current capacity for refrigeration of deceased persons, discuss mass fatality plans and identify temporary morgue sites, and determine the scope and volume of supplies needed to handle an increased number of deceased persons.

**Risk Communication**

Government and public health officials must communicate clearly and continuously with the public prior to and throughout a pandemic. To maintain public confidence and to enlist the support of individuals and families in disease containment efforts, public officials must provide unambiguous and consistent guidance on what individuals can do to protect themselves, how to care for family members at

home, when and where to seek medical care, and how to protect others and minimize the risks of disease transmission.

Individuals will, in general, respond to a pandemic and to public health interventions in ways that they perceive to be congruent with their interests and their instinct for self-preservation, and public health authorities should tailor their risk communication campaigns and interventions accordingly. The public will respond favorably to messages that acknowledge its concerns, allay anxiety and uncertainty, and provide clear incentives for desirable behavior. The information provided by public health officials should therefore be useful, addressing immediate needs, but it should also help private citizens recognize and understand the degree to which their collective actions will shape the course of a pandemic.

Providing regular messages through a single spokesperson with professional credibility is highly desirable. Conveying clinical information requires particular care to ensure that a lay audience can understand it. Distinguishing between political and professional messages is essential. Provisions should be made for communication in languages other than English and for those with disabilities.

Other important objectives for communication campaigns include providing information to the public about the status of the response; providing anticipatory guidance and dispelling unrealistic expectations regarding the delivery of health and medical care; providing guidance on how to obtain information about the status of missing persons; and providing information related to influenza complications, including where to seek help if people are having significant difficulties in coping with personal losses or fears about the pandemic.

### **Regulatory / Financial / Legal Matters**

More than one in four Americans receive health care coverage through Medicare, Medicaid, the State Children's Health Insurance Program (SCHIP), the Veterans Health Administration, TRICARE, or other Federal programs. Ensuring access to, and timely payment for, covered services during a pandemic will be critical to maintaining a functional health care infrastructure. It may also be necessary to extend certain waivers or develop incident-specific initiatives or coverage to facilitate access to care. Pandemic influenza response activities may exceed the budgetary resources of responding Federal and State government agencies, requiring compensatory legislative action.

Depending on the severity of a pandemic, certain requirements may be waived or revised to facilitate efficient delivery of health care services. For example, certain Emergency Medical Treatment and Active Labor Act (EMTALA), Medicare, Medicaid, SCHIP, and Health Insurance Portability and Accountability Act (HIPAA) requirements may be waived following a declaration of a public health emergency by the Secretary of HHS and a Presidential declaration of a major disaster or emergency. The authority to waive or amend legal requirements during a pandemic corresponds with the level of government that issues the requirements, whether Federal, State, or local. Statutes and rules may provide flexibility without waiver or revision. For example, HIPAA regulations allow covered entities to disclose patient information in circumstances that could arise during a pandemic, including disclosures: to provide treatment; to public health authorities for disease prevention and control and public health surveillance, investigations, and interventions; to lessen an imminent threat to health and safety; and to contact family members, guardians, or caretakers. In all cases, it will be important to make providers and institutions aware of the established legal framework, so that it is clear which authorities and regulations do or do not apply in a given situation.

Prior to the declaration of a public health emergency, State and local planners should examine existing State public health and medical licensing laws, interstate emergency management compacts and mutual aid agreements, and other legal and regulatory arrangements to determine the extent to which they meet potential new threats. Waivers granted at any level are likely to be targeted to an affected area for a temporary and specified period of time. In the case of an evolving pandemic, it will therefore be important to have the flexibility to extend or expand such waivers as needed.

## **Roles and Responsibilities**

The responsibility for preparing for, detecting, and responding to influenza outbreaks is shared by everyone. This includes private citizens, health care providers, the private sector, State, local, and tribal public health authorities, and the Federal Government. State, local, and tribal governments, the private sector, and the Federal Government all have important and interdependent roles in preparing for, responding to, and recovering from a pandemic. Effective management of the Nation's medical and public health response systems during a pandemic will require coordinated action by all segments of government and society.

State, local, and tribal governments are primarily responsible for detecting and responding to disease outbreaks and implementing measures to minimize the consequences of an outbreak. The Federal Government supports detection and response in many ways, including providing response personnel and expertise, response materiel, diagnostic reference services and testing support, and funding for certain response activities. It is anticipated that the potentially catastrophic nature of a pandemic may overwhelm local, State, and tribal capabilities. Federal agencies will be called upon to provide additional support, but even those resources may be overwhelmed at the peak of a pandemic.

### **The Federal Government**

The Federal Government will use all capabilities within its authority to support the private sector and State, local, and tribal public health authorities in preparedness and response activities. It will increase readiness to sustain essential Federal public health and medical functions during a pandemic and provide public health and medical support services under the *National Response Plan* (NRP). It will be prepared to advise State, local, and tribal governments and the medical and public health communities at large on how to deploy scarce medical resources, use and sequence community infection control measures, and address the medical challenges posed by pandemic influenza. It will perform surveillance for and monitor the progress of a pandemic on a national and international scale, support the development and production of medical countermeasures, and sponsor research on influenza viruses with pandemic potential. It will provide financial support and technical assistance to State, local, and tribal governments as they develop pandemic preparedness plans.

Department of Health and Human Services: HHS's primary responsibilities are those actions required to protect the health of all Americans, including communication of information related to pandemic influenza, leading international and domestic efforts in surveillance and detection of influenza outbreaks, ensuring the provision of essential human services, implementing measures to limit spread, and providing recommendations related to the use, distribution, and allocation of countermeasures and to the provision of care in mass casualty settings. HHS will support rapid containment of localized outbreaks domestically and provide guidance to State, local, and tribal public health authorities on the use, timing, and sequencing of community infection control measures. HHS also supports biomedical research and development of new vaccines and medical countermeasures.

Department of Homeland Security: Pursuant to Homeland Security Presidential Directive 7 (HSPD-7), DHS coordinates overall domestic incident management and Federal response procedures under the NRP and National Incident Management System (NIMS). Under the NRP, DHS is responsible for coordinating the protection of the Nation's critical infrastructure, and within the framework of Emergency Support Function #8 - Public Health and Medical Services (ESF #8) for the deployment of available NDMS medical, mortuary, and veterinary response assets.

Department of Defense: The primary responsibility of DOD is to preserve national security by protecting American forces, maintaining operational readiness, and sustaining critical military missions. DOD's first priority with respect to protecting human health will be to ensure sufficient capability to provide medical care to DOD forces and beneficiaries. DOD can provide medical, public health, transportation, logistical, communications, and other support consistent with existing legal authorities and to the extent that DOD's National Security preparedness is not compromised. Ideally, the human and technical resources of the National Guard should be balanced between support to the Governors of the individual States and the overall needs of national security.

Department of Veterans Affairs: VA provides health care, monetary benefits, and burial benefits to our Nation's veterans. VA's priority with respect to protecting human health is to deliver health care to enrolled veterans and beneficiaries. VA also has a mission to provide medical surge capacity for treatment of casualties arising from DOD operations and can provide other support to the extent that VA's mission to serve veterans is not compromised.

Department of Labor: DOL's primary responsibilities are those actions required to protect the health and safety of workers, including communication of information related to pandemic influenza to workers and employers, and other relevant activities.

### **State, Local, and Tribal Entities**

State, local, and tribal entities should have credible pandemic preparedness plans that address key response issues and outline strategies to mitigate the human, social, and economic consequences of a pandemic. They will initiate the request for the delivery and be primarily responsible for the distribution of medical countermeasures released from national stockpiles. States should be prepared to face challenges in the availability of essential commodities, demands for health care services that exceed existing capacity, and public pressure to enforce infection control measures in ways that may hinder the delivery of emergency services and supplies and exacerbate the economic repercussions of the pandemic. States, localities, and tribal entities should work to improve communication between public health departments and both private sector partners, such as health care facilities, community- and faith-based organizations, and clinical laboratories that are likely to be involved in the response to a pandemic. State, local, and tribal public health departments should coordinate their planning efforts with local Federal health care facilities.

### **The Private Sector and Critical Infrastructure Entities**

The private sector will play an integral role in preparedness before a pandemic begins and should be part of the national response. Businesses and corporations, especially those within sectors constituting the Nation's critical infrastructure, should develop continuity of operations plans that provide for workforce health protection and ensure that essential functions and vital services can be performed in the setting of significant absenteeism. Businesses and corporations should be prepared for public health interventions and recommendations that may increase absenteeism. Elements of the private sector concerned with

health care should be prepared to support local, State, national, and international efforts to contain or mitigate a pandemic.

### **Individuals and Families**

Private citizens must recognize and understand the degree to which their personal actions will govern the course of a pandemic. The success or failure of infection control measures is ultimately dependent upon the acts of individuals, and the collective response of 300 million Americans will significantly influence the shape of the pandemic and its medical, social, and economic outcomes (see *Individual, Family, and Community Response to Pandemic Influenza* between Chapters 5 and 6). Individuals will, in general, respond to a pandemic and to public health interventions in ways that they perceive to be congruent with their interests and their instinct for self-preservation, and public health authorities should tailor their risk communication campaigns and interventions accordingly. Institutions in danger of becoming overwhelmed will rely on the voluntarism and sense of civic and humanitarian duty of ordinary Americans. The talents and skills of individuals will prove crucial in our Nation's response to a pandemic.

## **Actions and Expectations**

### **6.1. Pillar One: Preparedness and Communication**

Preparedness and transparency are critical elements of the Strategy and the foundation of efforts to detect, contain, limit, delay, and mitigate a pandemic. Activities that should be undertaken before a pandemic to ensure preparedness and to communicate expectations and responsibilities to all levels of government and society are described below.

#### ***a. Planning for a Pandemic***

##### **6.1.1. Continue to work with States, localities, and tribal entities to establish and exercise pandemic response plans.**

- 6.1.1.1. The Federal Government shall, and State, local, and tribal governments should, define and test actions and priorities required to prepare for and respond to a pandemic, within 6 months. Measure of performance: completion and communication of national, departmental, State, local, and tribal pandemic influenza response plans; actions and priorities defined and tested.
- 6.1.1.2. HHS, in coordination with DHS, shall review and approve State Pandemic Influenza plans to supplement and support DHS State Homeland Security Strategies to ensure that Federal homeland security grants, training, exercises, technical, and other forms of assistance are applied to a common set of priorities, capabilities, and performance benchmarks, in conformance with the National Preparedness Goal, within 12 months. Measure of performance: definition of priorities, capabilities, and performance benchmarks; percentage of States with plans that address priorities, identify capabilities, and meet benchmarks.
- 6.1.1.3. DHS, in coordination with HHS, DOJ, DOT, and DOD, shall be prepared to provide emergency response element training (e.g., incident management, triage, security, and communications) and exercise assistance upon request of State,

local, and tribal communities and public health entities within 6 months.  
Measure of performance: percentage of requests for training and assistance fulfilled.

**6.1.2. Build upon existing domestic mechanisms to develop medical and veterinary surge capacity within or across jurisdictions to match medical requirements with capabilities.**

- 6.1.2.1. All health care facilities should develop and test infectious disease surge capacity plans that address challenges including: increased demand for services, staff shortages, infectious disease isolation protocols, supply shortages, and security.
- 6.1.2.2. HHS, in coordination with DHS, DOD, and VA, shall develop a joint strategy defining the objectives, conditions, and mechanisms for deployment under which NDMS assets, U.S. Public Health Service (PHS) Commissioned Corps, Epidemic Intelligence Service (EIS) officers, and DOD/VA health care personnel and public health officers would be deployed during a pandemic, within 9 months. Measure of performance: interagency strategy completed and tested for the deployment of Federal medical personnel during a pandemic.
- 6.1.2.3. HHS, in coordination with DHS, DOT, DOD, and VA, shall work with State, local, and tribal governments and leverage Emergency Management Assistance Compact agreements to develop protocols for distribution of critical medical materiel (e.g., ventilators) in times of medical emergency within 6 months. Measure of performance: critical medical material distribution protocols completed and tested.
- 6.1.2.4. HHS, in coordination with DOD and VA, in collaboration with medical professional and specialty societies, within their domains of expertise, shall develop guidance for allocating scarce health and medical resources during a pandemic, within 6 months. Measure of performance: guidance developed and disseminated.
- 6.1.2.5. HHS shall package and offer to the States and Territories the core operating components of an ESAR-VHP system within 6 months and encourage all States and tribal entities to implement the ESAR-VHP program by providing technical assistance and orientations at State and territory request to implement and operate Federal guideline (ESAR-VHP) compliant systems within 12 months. Measure of performance: guidance and technical assistance, as requested, provided to States to implement ESAR-VHP capability, compliant with Federal guidelines, in all States and U.S. territories.
- 6.1.2.6. HHS, in coordination with the USA Freedom Corps and Citizen Corps programs, shall continue to work with States and local communities to expand the Medical Reserve Corps program by 20 percent within 12 months. Measure of performance: increase number of Medical Reserve Corps units by 20 percent, from 350 to 420 units.



- 6.1.2.7. HHS, in coordination with DHS, DOD, VA and the USA Freedom Corps and Citizen Corps programs, shall prepare guidance for local Medical Reserve Corps coordinators describing the role of the Medical Reserve Corps during a pandemic, within 3 months. Measure of performance: guidance materials developed and published on Medical Reserve Corps website ([www.medicalreservecorps.gov](http://www.medicalreservecorps.gov)).
- 6.1.2.8. DHS, in coordination with the USA Freedom Corps, shall direct other Citizen Corps programs to prepare guidance detailing appropriate pandemic preparedness activities for each program, within 3 months. Measure of performance: guidance materials developed and published on Citizen Corps website and component program websites.

***b. Communicating Expectations and Responsibilities***

**6.1.3. Work to ensure clear, effective, and coordinated risk communication, domestically and internationally, before and during a pandemic. This includes identifying credible spokespersons at all levels of government to effectively coordinate and communicate helpful, informative messages in a timely manner.**

- 6.1.3.1. HHS, in coordination with DHS, DOS, DOD, VA, and other Federal partners, shall develop, test, and implement a Federal Government public health emergency communications plan (describing the government's strategy for responding to a pandemic, outlining U.S. international commitments and intentions, and reviewing containment measures that the government believes will be effective as well as those it regards as likely to be ineffective, excessively costly, or harmful) within 6 months. Measure of performance: containment strategy and emergency response materials completed and published on [www.pandemicflu.gov](http://www.pandemicflu.gov); communications plan implemented.
- 6.1.3.2. HHS, in coordination with DHS, shall develop, test, update and implement (if necessary) a multilingual and multimedia public engagement and risk communications strategy within 6 months. Measure of performance: risk communication material completed and published on [www.pandemicflu.gov](http://www.pandemicflu.gov) and other venues; State summit meetings held.
- 6.1.3.3. HHS, in coordination with DHS, DOD, and the VA, and in collaboration with State, local, and tribal health agencies and the academic community, shall select and retain opinion leaders and medical experts to serve as credible spokespersons to coordinate and effectively communicate important and informative messages to the public, within 6 months. Measure of performance: national spokespersons engaged in communications campaign.

**6.1.4. Provide guidance to the private sector and critical infrastructure entities on their role in the pandemic response, and considerations necessary to maintain essential services and operations despite significant and sustained worker absenteeism.**

- 6.1.4.1. State, local, and tribal public health and health care authorities, in collaboration with DHS, HHS, and the Department of Labor (DOL), should coordinate emer-

gency communication protocols with print and broadcast media, private industry, academic, and nonprofit partners within 6 months. Measure of performance: coordinated messages from communities identified above.

- 6.1.4.2. DOT, in cooperation with HHS, DHS, and DOC, shall develop model protocols for 9-1-1 call centers and public safety answering points that address the provision of information to the public, facilitate caller screening, and assist with priority dispatch of limited emergency medical services, within 12 months. Measure of performance: model protocols developed and disseminated to 9-1-1 call centers and public safety answering points.

### **c. Producing and Stockpiling Vaccines, Antiviral Medications, and Medical Material**

#### **6.1.5. Encourage and subsidize the development of State-based antiviral stockpiles to support response activities.**

- 6.1.5.1. HHS shall encourage and subsidize the development of State, territorial, and tribal antiviral stockpiles to support response activities within 18 months. Measure of performance: State, territorial, and tribal stockpiles established and antiviral medication purchases made toward goal of aggregate 31 million treatment courses.

#### **6.1.6. Ensure that our national stockpile and stockpiles based in States and communities are properly configured to respond to the diversity of medical requirements presented by a pandemic, including personal protective equipment, antibiotics, and general supplies.**

- 6.1.6.1. HHS, in coordination with DOD, VA, and State, local, and tribal partners, shall define the mix of antiviral medications to include in the Strategic National Stockpile (SNS) and State stockpiles and develop recommendations for how the different agents are to be used, within 6 months. Measure of performance: development of policy concerning the selection, relative proportions, and use of antiviral medications in SNS and State stockpiles.
- 6.1.6.2. HHS, in coordination with DOD, VA, and State, local, and tribal partners, shall define critical medical material requirements for stockpiling by the SNS and States to respond to the diversity of needs presented by a pandemic, within 9 months. Measure of performance: requirements defined and guidance provided on stockpiling.
- 6.1.6.3. DOD, as part of its departmental implementation plan, shall conduct a medical materiel requirements gap analysis and procure necessary materiel to enhance Military Health System surge capacity, within 18 months. Measure of performance: gap analysis completed and necessary materiel procured.
- 6.1.6.4. HHS, DOD, VA and the States shall maintain antiviral and vaccine stockpiles in a manner consistent with the requirements of FDA's Shelf Life Extension Program (SLEP) and explore the possibility of broadening SLEP to include equivalently maintained State stockpiles, within 6 months. Measure of performance:



compliance with SLEP requirements documented; decision made on broadening SLEP to State stockpiles.

**6.1.7. Establish domestic production capacity and stockpiles of countermeasures to ensure sufficient antiviral medications and vaccine for front-line personnel and at-risk populations, including military personnel.**

- 6.1.7.1. HHS, in coordination with DHS, DOJ, VA, and in collaboration with State, local, and tribal partners, shall determine the national medical countermeasure requirements to ensure the sustained functioning of medical, emergency response, and other front-line organizations, within 12 months. Measure of performance: more specific definition of sectors and personnel for priority access to medical countermeasures and quantities needed to protect those groups; guidance provided to State, local, and tribal governments and to infrastructure sectors for various scenarios of pandemic severity and medical countermeasure supply.
- 6.1.7.2. HHS shall establish and maintain stockpiles of pre-pandemic vaccines adequate to immunize 20 million persons against influenza strains that present a pandemic threat, as soon as possible within the constraints of industrial capacity. Measure of performance: procurement of 20 million courses of pre-pandemic vaccine against influenza strains presenting a pandemic threat.
- 6.1.7.3. HHS in collaboration with State/local partners shall procure and allocate sufficient stockpiles of countermeasures to ensure continuity of critical medical and emergency response operations, within 18 months, within the constraints of industrial capacity. Measure of performance: sufficient quantities of antiviral medications and other countermeasures procured and distributed between SNS and State stockpiles.
- 6.1.7.4. DOD shall establish stockpiles of vaccine against H5N1 and other influenza subtypes determined to represent a pandemic threat adequate to immunize approximately 1.35 million persons for military use within 18 months of availability. Measure of performance: sufficient vaccine against each influenza virus determined to represent a pandemic threat in DOD stockpile to vaccinate 1.35 million persons.

**6.1.8. Establish domestic production capacity and stockpiles of countermeasures to ensure sufficient vaccine to vaccinate the entire U.S. population within 6 months of the emergence of a virus with pandemic potential.**

- 6.1.8.1. HHS shall work with the pharmaceutical industry toward the goal of developing, within 60 months, domestic vaccine production capacity sufficient to provide vaccine for the entire U.S. population within 6 months after the development of a vaccine reference strain. Measure of performance: domestic vaccine manufacturing capacity in place to produce 300 million courses of vaccine within 6 months of development of a vaccine reference strain during a pandemic.

**6.1.9. Establish domestic production capacity and stockpiles of countermeasures to ensure antiviral treatment for those who contract a pandemic strain of influenza.**

- 6.1.9.1. HHS shall, to the extent feasible, work with antiviral drug manufacturers and large distributors to develop agreements supporting the Federal procurement of available stocks of antiviral drugs both during the pre-pandemic and pandemic periods, within 12 months. Measure of performance: new antiviral medications procured by SNS, within the constraints of industrial capacity; Federal contracts in place with antiviral drug manufacturers and distributors.
- 6.1.9.2. HHS, in collaboration with the States, shall purchase sufficient quantities of antiviral drugs to treat 25 percent of the U.S. population, with reserve of 6 million treatment courses for outbreak containment within 18 months, within the constraints of industrial capacity. Measure of performance: 50 million treatment courses of antiviral drugs procured by SNS; States and tribes make stockpile purchases toward aggregate 31 million treatment course goal.
- 6.1.9.3. DOD shall procure 2.4 million treatment courses of antiviral medications and position them at locations worldwide within 18 months. Measure of performance: aggregate 2.4 million treatment courses of antiviral medications in DOD stockpiles.

**6.1.10. Facilitate appropriate coordination of efforts across the vaccine manufacturing sector.**

- 6.1.10.1. HHS, in coordination with the private sector, shall assess the ability of U.S.-based pharmaceutical manufacturing facilities to contribute surge capacity and to retrofit existing facilities for pandemic vaccine production. This assessment will be completed within 6 months and should inform efforts to expand vaccine capacity. Measure of performance: completed assessment.
- 6.1.10.2. HHS, in coordination with DHS, DOD, VA, DOC, DOJ, and Treasury, shall assess within whether use of the Defense Production Act or other authorities would provide sustained advantages in procuring medical countermeasures, within 6 months. Measure of performance: analytical report completed on the advantages/disadvantages of invoking the Defense Production Act to facilitate medical countermeasure production and procurement.

**6.1.11. Address regulatory and other legal issues to the expansion of our domestic vaccine production capacity.**

- 6.1.11.1. HHS shall assess its existing authorities and develop a plan of action to address any regulatory or other legal issues related to the expansion of domestic vaccine production capacity within 12 months. Measure of performance: regulatory and legal issues identified in assessment.
- 6.1.11.2. HHS shall develop a protocol and decision tools to implement liability protections and compensation, as authorized by the Public Readiness and Emergency Preparedness Act (Pub. L. 109-148), within 6 months. Measure of performance: publication of protocol and decision tools.

**6.1.12. Expand the public health recommendations for domestic seasonal influenza vaccination and encourage the same practice internationally.**

- 6.1.12.1. HHS shall collaborate with health care providers, industry partners, and State, local, and tribal public health authorities to develop public information campaigns and other mechanisms to stimulate increased seasonal influenza vaccination, within 12 months. Measure of performance: domestic vaccine use increased relative to historical norms.

***d. Establishing Distribution Plans for Medical Countermeasures, Including Vaccines and Antiviral Medications*****6.1.13. Develop credible countermeasure distribution mechanisms for vaccine and antiviral agents prior to and during a pandemic.**

- 6.1.13.1. HHS, in coordination with DHS, DOD, VA, and DOJ, and in collaboration with State, local, and tribal partners and the private sector, shall ensure that States, localities, and tribal entities have developed and exercised pandemic influenza countermeasure distribution plans, and can enact security protocols if necessary, according to pre-determined priorities (see below) within 12 months. Measures of performance: ability to activate, deploy, and begin distributing contents of medical stockpiles in localities as needed established and validated through exercises.
- 6.1.13.2. HHS, in coordination with DOD, VA, States, and other public sector entities with antiviral drug stockpiles, shall coordinate use of assets maintained by different organizations, within 12 months. Measure of performance: plans developed for coordinated use of antiviral stockpiles.
- 6.1.13.3. HHS, in collaboration with State, territorial, tribal, and local health care delivery partners, shall develop and execute strategies to effectively implement target group recommendations described below, within 12 months. Measure of performance: guidance on strategies to implement target group recommendations developed and disseminated to State, local, and tribal authorities for inclusion in pandemic response plans.
- 6.1.13.4. HHS, in coordination with DOD, VA, and in collaboration with State, local, and tribal governments and private sector partners, shall assist in the development of distribution plans for medical countermeasure stockpiles to ensure that delivery and distribution algorithms have been planned for each locality for antiviral distribution. Goal is to be able to distribute antiviral medications to infected patients within 48 hours of the onset of symptoms within 12 months. Measure of performance: distribution plans developed.
- 6.1.13.5. HHS, in coordination with DHS, DOS, DOD, DOL, VA, and in collaboration with State, local, and tribal governments and private sector partners, shall develop plans for the allocation, distribution, and administration of pre-pandemic vaccine, within 9 months. Measure of performance: department plans developed and guidance disseminated to State, local, and tribal authorities

to facilitate development of pandemic response plans.

- 6.1.13.6. DOT, in coordination with HHS, DHS, State, local, and tribal officials and other EMS stakeholders, shall develop suggested EMS pandemic influenza guidelines for statewide adoption that address: clinical standards, education, treatment protocols, decontamination procedures, medical direction, scope of practice, legal parameters, and other issues, within 12 months. Measure of performance: EMS pandemic influenza guidelines completed.
- 6.1.13.7. HHS, in coordination with DHS, DOT, DOD, and VA, shall work with State, local, and tribal governments and private sector partners to develop and test plans to allocate and distribute critical medical materiel (e.g., ventilators with accessories, resuscitator bags, gloves, face masks, gowns) in a health emergency, within 6 months. Measure of performance: plans developed, tested, and incorporated into department plan, and disseminated to States and tribes for incorporation into their pandemic response plans.
- 6.1.13.8. DOD shall supply military units and posts, installations, bases, and stations with vaccine and antiviral medications according to the schedule of priorities listed in the DOD pandemic influenza policy and planning guidance, within 18 months. Measure of performance: vaccine and antiviral medications procured; DOD policy guidance developed on use and release of vaccine and antiviral medications; and worldwide distribution drill completed.
- 6.1.13.9. HHS, in coordination with DOD, VA, and in collaboration with State, territorial, tribal, and local partners, shall develop/refine mechanisms to: (1) track adverse events following vaccine and antiviral administration; (2) ensure that individuals obtain additional doses of vaccine, if necessary; and (3) define protocols for conducting vaccine- and antiviral-effectiveness studies during a pandemic, within 18 months. Measure of performance: mechanism(s) to track vaccine and antiviral medication coverage and adverse events developed; vaccine- and antiviral-effectiveness study protocols developed.
- 6.1.13.10. DOJ, in coordination with HHS, DHS, DOS, and DOC, shall lead the development of a joint strategic plan to ensure international shipments of counterfeit vaccine and antiviral medications are detected at our borders and that domestic counterfeit drug production and distribution is thwarted through aggressive enforcement efforts. Measure of performance: joint strategic plan developed; international and domestic counterfeit drug shipments prevented or interdicted.
- 6.1.14. Prioritize countermeasure allocation before an outbreak, and update this prioritization immediately after the outbreak begins based on the at-risk populations, available supplies, and the characteristics of the virus.**
  - 6.1.14.1. HHS, in coordination with DHS and Sector-Specific Agencies, DOS, DOD, DOJ, DOL, VA, Treasury, and State/local governments, shall develop objectives for the use of, and strategy for allocating, vaccine and antiviral drug stockpiles during pre-pandemic and pandemic periods under varying conditions of countermeasure supply and pandemic severity within 3 months. Measure of performance:

clearly articulated statement of objectives for use of medical countermeasures under varying conditions of supply and pandemic severity.

- 6.1.14.2. HHS, in coordination with DHS and Sector-Specific Agencies, DOS, DOD, DOL, VA, Treasury, and State/local governments, shall identify lists of personnel and high-risk groups who should be considered for priority access to medical countermeasures, under various pandemic scenarios, according to strategy developed in compliance with 6.1.14.1, within 9 months. Measure of performance: provisional recommendations of groups who should receive priority access to vaccine and antiviral drugs established for various scenarios of pandemic severity and medical countermeasure supply.
- 6.1.14.3. HHS, in coordination with DHS and Sector-Specific Agencies, DOS, DOD, DOL, and VA, shall establish a strategy for shifting priorities based on at-risk populations, supplies and efficacy of countermeasures against the circulating pandemic strain, and characteristics of the virus within 9 months. Measure of performance: clearly articulated process in place for evaluating and adjusting pre-pandemic recommendations of groups receiving priority access to medical countermeasures.
- 6.1.14.4. HHS, in coordination with DHS and Sector-Specific Agencies, DOS, DOD, DOL, VA, and Treasury, shall present recommendations on target groups for vaccine and antiviral drugs when sustained and efficient human-to-human transmission of a potential pandemic influenza strain is documented anywhere in the world. These recommendations will reflect data from the pandemic and available supplies of medical countermeasures. Measure of performance: provisional identification of priority groups for various pandemic scenarios through inter-agency process within 2-3 weeks of outbreak.

***e. Advancing Scientific Knowledge and Accelerating Development***

**6.1.15. Ensure that there is maximal sharing of scientific information about influenza viruses between governments, scientific entities, and the private sector.**

- 6.1.15.1. HHS shall develop capability, protocols, and procedures to ensure that viral isolates obtained during investigation of human outbreaks of influenza with pandemic potential are sequenced and that sequences are published on GenBank within 1 week of confirmation of diagnosis in index case, within 6 months. Measure of performance: viral isolate sequences from outbreaks published on GenBank within 1 week of confirmation of diagnosis.
- 6.1.15.2. HHS shall increase and accelerate genomic sequencing of known human and avian influenza viruses and shall rapidly make this sequence information publicly available, within 6 months. Measure of performance: increased throughput of genomes sequenced (versus FY 2005 baseline) and decreased time interval between completion of sequencing and publication on GenBank.
- 6.1.15.3. HHS shall develop protocols and procedures to ensure timely reporting to Federal agencies and submission for publication of data from HHS-supported

influenza vaccine, antiviral medication, and diagnostic evaluation studies, within 6 months. Measure of performance: study data shared with Federal agencies within 1 month of analysis and publication of clinical trial data following completion of studies.

**6.1.16. Accelerate the development of cell culture technology for influenza vaccine production and establish a domestic production base to support vaccination demands.**

- 6.1.16.1. HHS shall continue to support the advanced development of cell-culture based influenza vaccine candidates. Measure of performance: research grants and/or contracts awarded to develop cell-culture based influenza vaccines against currently circulating influenza strains with pandemic potential within 6 months.
- 6.1.16.2. HHS shall support the renovation of existing U.S. manufacturing facilities that produce other FDA-licensed cell-based vaccines or biologics and the establishment of new domestic cell-based influenza vaccine manufacturing facilities, within 36 months. Measure of performance: contracts awarded for renovation or establishment of domestic cell-based influenza vaccine manufacturing capacity.

**6.1.17. Use novel investment strategies to advance the development of next-generation influenza diagnostics and countermeasures, including new antiviral medications, vaccines, adjuvant technologies, and countermeasures that provide protection across multiple strains and seasons of the influenza virus.**

- 6.1.17.1. HHS shall continue to support the development and clinical evaluation of novel vaccines and vaccination strategies (e.g., adjuvants, alternative delivery systems, common epitope vaccines). Measure of performance: research grants and/or contracts awarded to support the development of influenza vaccines (including polyvalent influenza vaccines), adjuvants and dose-sparing strategies, and more efficient delivery systems within 12 months, leading to initiation of phase I and II clinical trials to evaluate influenza vaccines and vaccination strategies.
- 6.1.17.2. HHS shall collaborate with the pharmaceutical, medical device, and diagnostics industries to accelerate development, evaluation (including the evaluation of dose-sparing strategies), licensure, and U.S.-based production of new antiviral drugs and diagnostics. Development activities should include design of preclinical and clinical studies to collect safety and efficacy information across multiple strains and seasons of circulating influenza illness, and advance design of protocols to obtain additional updated information to support revisions in product usage during circulation of novel strains and evolution of pandemic spread. Such collaborations should involve early and frequent discussions with the FDA to explore the use of accelerated regulatory pathways towards product approval or licensure. Collaborations concerning diagnostic tests should include CDC to facilitate access to pandemic virus samples for validation testing and ensure that the test is one that can be used to promote and protect the public health during an influenza pandemic. Measure of performance: initiation of clinical trials of new influenza antiviral drugs and diagnostics.



- 6.1.17.3. HHS, in coordination with DHS, shall develop and test new point-of-care and laboratory-based rapid influenza diagnostics for screening and surveillance, within 18 months. Measure of performance: new grants and contracts awarded to researchers to develop and evaluate new diagnostics.
- 6.1.17.4. HHS shall increase access to standardized influenza reagents for use in influenza tests and research, within 6 months. Measure of performance: standardized influenza reagents distributed to domestic and international partners within 3 business days of a request.

## **6.2. Pillar Two: Surveillance and Detection**

The ability to contain or delay the spread of pandemic influenza depends critically upon the early detection of outbreaks. Within the United States, we will work to establish surveillance systems and reporting mechanisms that provide continuous, real-time “situational awareness” to public health authorities at all levels of government. We will also work to enhance laboratory capacity, develop new and improved rapid diagnostic tests, and consolidate real-time analytical and modeling capabilities to support response activities.

### ***a. Ensuring Rapid Reporting of Outbreaks***

- 6.2.1. Support the development and sustainment of sufficient U.S. and host nation laboratory capacity and diagnostic reagents in affected regions and domestically, to provide rapid confirmation of cases in animals or humans.**
  - 6.2.1.1. HHS shall provide guidance to public health and clinical laboratories on the different types of diagnostic tests and the case definitions to use for influenza at the time of each pandemic phase. Guidelines for the current pandemic alert phase will be disseminated within 3 months. Measure of performance: dissemination on [www.pandemicflu.gov](http://www.pandemicflu.gov) and through other channels of guidance on the use of diagnostic tests for H5N1 and other potential pandemic influenza subtypes.
  - 6.2.1.2. HHS shall ensure that testing by reverse transcriptase-polymerase chain reaction (RT-PCR) for H5N1 and other influenza viruses with pandemic potential is available at LRN laboratories and CDC within 3 months. Measure of performance: RT-PCR for H5N1 and other potential pandemic influenza subtypes and strains in use at CDC and LRN laboratories.
  - 6.2.1.3. HHS, in coordination with DOD, VA, USDA, DHS, EPA, and other partners, in collaboration with its LRN Reference Laboratories, shall be prepared within 6 months to conduct laboratory analyses to detect pandemic subtypes and strains in referred specimens and conduct confirmatory testing, as requested. Measure of performance: initial testing and identification of suspect pandemic influenza specimens completed at LRN Reference and National Laboratories within 24 hours.
  - 6.2.1.4. All Federal, State, local, tribal, and private sector medical facilities should ensure that protocols for transporting influenza specimens to appropriate reference

laboratories are in place within 3 months. Measure of performance: transportation protocols for laboratory specimens detailed in HHS, DOD, VA, State, territorial, tribal, and local pandemic response plans.

- 6.2.1.5. State, local, and tribal entities should be prepared, in the event of a pandemic, to increase diagnostic testing for influenza and increase the frequency of reporting to CDC.

**6.2.2. Advance mechanisms for “real-time” clinical surveillance in domestic acute care settings such as emergency departments, intensive care units, and laboratories to provide tribal, local, State, and Federal public health officials with continuous awareness of the profile of illness in communities, and leverage all Federal medical capabilities, both domestic and international, in support of this objective.**

- 6.2.2.1. HHS shall be prepared to provide ongoing information from the national influenza surveillance system on the pandemic’s impact on health and the health care system, within 6 months. Measure of performance: surveillance data aggregated and disseminated every 7 days, or as often as the situation warrants, to DHS, Sector-Specific Agencies, and State, territorial, tribal, and local partners.
- 6.2.2.2. HHS, in coordination with Federal, State, local, tribal, and private sector partners, shall develop real-time (same-day) tracking capabilities of pneumonia or influenza hospitalizations and influenza deaths to enhance its surveillance capabilities at the onset of and during a pandemic, within 12 months. Measure of performance: real-time (same-day) nationwide hospital census and mortality tracking system is operational for use during a pandemic.
- 6.2.2.3. HHS, in coordination with DOD and VA, shall expand the number of hospitals and cities participating in the BioSenseRT program to improve the Nation’s capabilities for disease detection, monitoring, and situational awareness within 12 months. Measure of performance: number of hospitals (including DOD and VA facilities) participating in the BioSenseRT program increased to 350 hospitals in 42 cities.
- 6.2.2.4. HHS shall reduce the time between reporting of virologic laboratory data from State, local, tribal, and private sector partners and collation, analysis, and reporting to key stakeholders, within 6 months. Measure of performance: time delay between receipt of data and collation, analysis, and reporting of results of 7 days or less.
- 6.2.2.5. HHS shall increase the frequency of reporting and the number and geographic location of reporting health care providers from which outpatient surveillance data are collected through the Sentinel Provider Network (SPN), the Emerging Infections Program (EIP) influenza project, and the New Vaccine Surveillance Network (NVSN), within 6 months. Measure of performance: number of reporting healthcare providers increased to one or more per 250,000 population.
- 6.2.2.6. HHS shall improve the speed at which it performs mortality surveillance through the 122 Cities Mortality Reporting System within 3 months. Measure of



performance: mortality data collected at CDC within 1 week of decedent's demise increased by 25 percent compared with 2005.

- 6.2.2.7. DHS, in collaboration with HHS, DOD, VA, USDA, and other Federal departments and agencies with biosurveillance capabilities and real-time data sources, shall enhance NBIS capabilities to ensure the availability of a comprehensive and all-source biosurveillance common operating picture throughout the Interagency, within 12 months. Measure of performance: NBIS provides integrated surveillance data to DHS, HHS, USDA, DOD, VA, and other interested interagency customers.
- 6.2.2.8. HHS, in coordination with DHS, DOD, and VA, and in collaboration with State, local, and tribal authorities, shall be prepared to collect, analyze, integrate, and report information about the status of hospitals and health care systems, health care critical infrastructure, and medical materiel requirements, within 12 months. Measure of performance: guidance provided to States and tribal entities on the use and modification of the components of the National Hospital Available Beds for Emergencies and Disasters (HAvBED) system for implementation at the local level.
- 6.2.2.9. DOD shall enhance influenza surveillance efforts within 6 months by: (1) ensuring that medical treatment facilities (MTFs) monitor the Electronic Surveillance System for Early Notification of Community-based Epidemics (ESSENCE) and provide additional information on suspected or confirmed cases of pandemic influenza through their Service surveillance activities; (2) ensuring that Public Health Emergency Officers (PHEOs) report all suspected or actual cases through appropriate DOD reporting channels, as well as to CDC, State public health authorities, and host nations; and (3) posting results of aggregated surveillance on the DOD Pandemic Influenza Watchboard; all within 18 months. Measure of performance: number of MTFs performing ESSENCE surveillance greater than 80 percent; DOD reporting policy for public health emergencies, including pandemic influenza completed.
- 6.2.2.10. State, local, and tribal public health departments should develop relationships with hospitals and health care systems within their jurisdictions to facilitate collection of real-time or near real-time clinical surveillance data from domestic acute care settings such as emergency departments, intensive care units, and laboratories.
- 6.2.2.11. State, local, and tribal public health departments should provide weekly reports on the overall level of influenza activity in their States or localities, with assistance from CDC epidemiologists and field officers posted within each State health department in collecting and reporting these data.
- 6.2.3. **Develop and deploy rapid diagnostics with greater sensitivity and reproducibility to allow onsite diagnosis of pandemic strains of influenza at home and abroad, in animals and humans, to facilitate early warning, outbreak control, and targeting of antiviral therapy.**

- 6.2.3.1. HHS, in coordination with DHS and DOD, shall work with pharmaceutical and medical device company partners to develop and evaluate rapid diagnostic tests for novel influenza subtypes including H5N1 within 18 months. Measure of performance: new investment in research to develop influenza diagnostics; new rapid diagnostic tests, if found to be useful, are available for influenza testing, including for novel influenza subtypes.
- 6.2.3.2. HHS, in coordination with DHS, DOD, and VA, shall compile an inventory of all research and product development work on rapid diagnostic testing for influenza and shall reach consensus on sets of requirements meeting national needs and a common test methodology to drive further private-sector investment and product development, within 6 months. Measure of performance: inventory developed and requirements paper disseminated.
- 6.2.3.3. HHS, in coordination with DOD, VA, and DHS, shall encourage and expedite private-sector development of rapid subtype- and strain-specific influenza point-of-care tests within 12 months of the publication of requirements. Measure of performance: rapid point-of-care test available in the marketplace within 18 months.
- 6.2.3.4. HHS-, DOD-, and VA-funded hospitals and health facilities shall have access to improved rapid diagnostic tests for influenza A, including influenza with pandemic potential, within 6 months of when tests become available.
- 6.2.3.5. State, local, and tribal public health departments should acquire and deploy rapid diagnostic tests that are specific and sensitive for pandemic influenza strains, as soon as those tests are available. Measure of performance: diagnostic tests, if found to be useful, are accessible to federally funded health facilities.

***b. Using Surveillance to Limit Spread***

**6.2.4. Develop and exercise mechanisms to provide active and passive surveillance during an outbreak, both within and beyond our borders.**

- 6.2.4.1. HHS, in coordination with DHS, DOD, VA, USDA, and DOS, shall be prepared, within 12 months, to continuously evaluate surveillance and disease reporting data to determine whether ongoing disease containment and medical counter-measure distribution and allocation strategies need to be altered as a pandemic evolves. Measure of performance: analyses of surveillance data performed at least weekly during an outbreak with timely adjustment of strategic and tactical goals, as required.
- 6.2.4.2. DHS, in coordination with Sector-Specific Agencies, HHS, DOD, DOJ, and VA, and in collaboration with the private sector, shall be prepared to track integrity of critical infrastructure function, including the health care sector, to determine whether ongoing strategies of ensuring workplace safety and operational continuity need to be altered as a pandemic evolves, within 6 months. Measure of performance: tracking system in place to monitor integrity of critical infrastructure function and operational continuity in near real time.

- 6.2.4.3. DOD and VA shall be prepared to track and provide personnel and beneficiary health statistics and develop enhanced methods to aggregate and analyze data documenting influenza-like illness from its surveillance systems within 12 months. Measure of performance: influenza tracking systems in place and capturing beneficiary clinical encounters.

**6.2.5. Develop rapid-response modeling capability to improve decision making during a pandemic.**

- 6.2.5.1. HHS, in coordination with DOD and DHS, shall develop and maintain a real-time epidemic analysis and modeling hub that will explore and characterize response options as a support to policy and decision makers within 6 months. Measure of performance: modeling center with real-time epidemic analysis capabilities established.

**6.3. Pillar Three: Response and Containment**

In approaching the problem of pandemic influenza, the U.S. Government endorses a layered strategy of response and containment. As outlined in the other chapters of this document, the United States is working with other nations and relevant international organizations to detect and contain outbreaks of animal influenza with pandemic potential with the aim of preventing its spread to humans. In the event of sustained and efficient human-to-human transmission of an influenza virus with pandemic potential, all reasonable actions to contain the epidemic at its source and to delay its introduction to the United States should be attempted. If such efforts fail, all instruments of national power will be directed to limiting or otherwise delaying the spread of disease; minimizing suffering and death; sustaining critical infrastructure and a Constitutional form of government; and reducing the economic and social effects of the pandemic.

***a. Containing Outbreaks***

**6.3.1. Encourage all levels of government, domestically and globally, to take appropriate and lawful action to contain an outbreak within the borders of their community, province, State, or nation.**

- 6.3.1.1. State, local, and tribal pandemic preparedness plans should address the implementation and enforcement of isolation and quarantine, the conduct of mass immunization programs, and provisions for release or exception.

**6.3.2. Provide guidance, including decision criteria and tools, to all levels of government on the range of options for infection control and containment, including those circumstances where social distancing measures, limitations on gatherings, or quarantine authority may be an appropriate public health intervention.**

- 6.3.2.1. HHS, in coordination with DHS, DOT, Education, DOC, DOD, and Treasury, shall provide State, local, and tribal entities with guidance on the combination, timing, evaluation, and sequencing of community containment strategies (including travel restrictions, school closings, snow days, self-shielding, and quarantine during a pandemic) based on currently available data, within 6 months, and update this guidance as additional data becomes available. Measure

of performance: guidance provided on community influenza containment measures.

- 6.3.2.2. HHS shall provide guidance on the role and evaluation of the efficacy of geographic quarantine in efforts to contain an outbreak of influenza with pandemic potential at its source, within 3 months. Measure of performance: guidance available within 72 hours of initial outbreak.
- 6.3.2.3. HHS, in coordination with DHS and DOD and in collaboration with mathematical modelers, shall complete research identifying optimal strategies for using voluntary home quarantine, school closure, snow day restrictions, and other community infection control measures, within 12 months. Measure of performance: guidance developed and disseminated on the use of community control.
- 6.3.2.4. As appropriate, DOD, in consultation with its Combatant Commanders (COCOM), shall implement movement restrictions and individual protection and social distancing strategies (including unit shielding, ship sortie, cancellation of public gatherings, drill, training, etc.) within their posts, installations, bases, and stations. DOD personnel and beneficiaries living off-base should comply with local community containment guidance with respect to activities not directly related to the installation. DOD shall be prepared to initiate within 18 months. Measure of performance: the policies/procedures are in place for at-risk DOD posts, installations, bases, stations, and for units to conduct an annual training evaluation that includes restriction of movement, shielding, personnel protection measures, health unit isolation, and other measures necessary to prevent influenza transmission.
- 6.3.2.5. All HHS-, DOD-, and VA-funded hospitals and health facilities shall develop, test, and be prepared to implement infection control campaigns for pandemic influenza, within 3 months. Measure of performance: guidance materials on infection control developed and disseminated on [www.pandemicflu.gov](http://www.pandemicflu.gov) and through other channels.
- 6.3.2.6. All health care facilities should develop, test, and be prepared to implement infection control campaigns for pandemic influenza, within 6 months.
- 6.3.2.7. HHS, in coordination with DHS, DOC, DOL, and Sector-Specific Agencies, and in collaboration with medical professional and specialty societies, shall develop and disseminate infection control guidance for the private sector, within 12 months. Measure of performance: validated, focus group-tested guidance developed, and published on [www.pandemicflu.gov](http://www.pandemicflu.gov) and in other forums.

**6.3.3. Emphasize the roles and responsibilities of the individual in preventing the spread of an outbreak, and the risk to others if infection control practices are not followed.**

- 6.3.3.1. HHS, in coordination with DHS, VA, and DOD, shall develop and disseminate guidance that explains steps individuals can take to decrease their risk of acquiring or transmitting influenza infection during a pandemic, within 3

months. Measure of performance: guidance disseminated on [www.pandemicflu.gov](http://www.pandemicflu.gov) and through VA and DOD channels.

- 6.3.3.2. HHS, in coordination with DHS, DOD, VA, and DOT and in collaboration with State, local, and tribal partners, shall develop and disseminate lists of social distancing behaviors that individuals may adopt within 6 months and update guidance as additional data becomes available. Measure of performance: guidance disseminated on [www.pandemicflu.gov](http://www.pandemicflu.gov) and through other channels.

***b. Leveraging National Medical and Public Health Surge Capacity***

**6.3.4. Implement State, local, and tribal public health and medical surge plans, and leverage all Federal medical facilities, personnel, and response capabilities to support the national surge requirement.**

- 6.3.4.1. Major medical societies and organizations, in collaboration with HHS, DHS, DOD, and VA, should develop and disseminate protocols for changing clinical care algorithms in settings of severe medical surge. Measure of performance: evidence-based protocols developed to optimize care that can be provided in conditions of severe medical surge.
- 6.3.4.2. HHS, in coordination with DHS, DOD, and VA, and in collaboration with States, localities, tribal entities, and private sector health care facilities, shall develop strategies and protocols for expanding hospital and home health care delivery capacity in order to provide care as effectively and equitably as possible, within 6 months. Measure of performance: guidance and protocols developed and disseminated.
- 6.3.4.3. HHS shall work with State Medicaid and SCHIP programs to ensure that Federal standards and requirements for reimbursement or enrollment are applied with the flexibilities appropriate to a pandemic, consistent with applicable law. Preliminary strategies shall be developed within 6 months. Measure of performance: draft policies and guidance developed concerning emergency enrollment in and reimbursement through State Medicaid and SCHIP programs during a pandemic.
- 6.3.4.4. DHS assets, including NDMS medical materiel and mobile medical units, and HHS assets, such as the USPHS Commissioned Corps and FMSs, shall be deployed in a manner consistent with pre-defined strategic considerations. Measure of performance: development, within 6 months, of strategic principles for deployment of Federal medical assets in a pandemic; consistency of deployments during a pandemic with these principles.
- 6.3.4.5. DHS shall activate NDMS teams, if available, to augment efforts of State, local, and tribal governments as part of the Federal response. Measure of performance: number of NDMS teams activated and deployed during a pandemic.
- 6.3.4.6. HHS shall deploy the USPHS Commissioned Corps and FMSs, if available and in combination or separately as circumstances warrant, to augment efforts of

State/local governments as part of the Federal response. Measure of performance: USPHS Commissioned Corps personnel trained on FMSs within 9 months; Commissioned Corps personnel and FMSs deployed within 72 hours of order to mobilize during a pandemic.

6.3.4.7. DOD shall enhance its public health response capabilities by: (1) continuing to assign epidemiologists and preventive medicine physicians within key operational settings; (2) expanding ongoing DOD participation in CDC's EIS Program; and (3) within 18 months, fielding specific training programs for PHEOs that address their roles and responsibilities during a public health emergency. Measure of performance: all military PHEOs fully trained within 18 months; increase military trainees in CDC's EIS program by 100 percent within 5 years.

6.3.4.8. All hospitals should be prepared to treat patients with pandemic influenza (i.e., equipped and ready to care for: (1) a limited number of patients infected with a pandemic influenza virus, or other novel strain of influenza, as part of normal operations; and (2) a large number of patients in the event of escalating transmission of pandemic influenza).

6.3.4.9. All hospitals and health care systems should develop, test, and be ready to employ business continuity plans and identify the critical links in their supply chains as well as sources of emergency.

6.3.4.10. All health care systems, individually or collaborating with other facilities to develop local or regional stockpiles maintained under vendor managed inventory systems, should consider stockpiling consumable critical medical materiel (including but not limited to food, fuel, water, N95 respirators, surgical and /or procedural masks, gowns, and ethyl-alcohol based gels) sufficient for the peak period of a pandemic wave (2-3 weeks).

**6.3.5. Activate plans to distribute medical countermeasures, including non-medical equipment and other material, from the Strategic National Stockpile and other distribution centers to Federal, State, local, and tribal authorities.**

6.3.5.1. HHS, in coordination with DHS, DOL, Education, VA, and DOD, shall develop and disseminate guidance and educational tools that explain steps individuals can take to decrease their risk of acquiring or transmitting influenza infection during a pandemic, within 6 months. Measure of performance: interim guidance disseminated on [www.pandemicflu.gov](http://www.pandemicflu.gov) and through VA, DOD, and other channels within 3 months; complementary educational tools on social distancing, personal hygiene, mask use, and other infection control precautions developed within 6 months.

6.3.5.2. HHS, in collaboration with State, local, and tribal governments, shall develop and disseminate recommendations for the use, if any, of antiviral stockpiles for targeted post-exposure prophylaxis in civilian populations, within 3 months. Measure of performance: States, localities, and tribal entities have received recommendations for incorporation into response plans.



6.3.5.3. HHS, in coordination with DHS, shall allocate and assure the effective and secure distribution of public stocks of antiviral drugs and vaccines when they become available. HHS and DHS are currently prepared to distribute stockpile as soon as countermeasures become available. Measure of performance: number of doses of vaccine and treatment courses of antiviral medications distributed.

**6.3.6. Address barriers to the flow of public health, medical, and veterinary personnel across State and local jurisdictions to meet local shortfalls in public health, medical, and veterinary capacity.**

6.3.6.1. Prior to the declaration of a public health emergency, State, local, and tribal public health authorities should examine existing Federal laws, regulations, and requirements, State public health and medical licensing laws, the provisions of interstate emergency management compacts and mutual aid agreements, and other legal and regulatory arrangements to determine the extent to which they address barriers to the flow of qualified public health and medical personnel across jurisdictional lines or between health care facilities.

***c. Sustaining Infrastructure, Essential Services, and the Economy***

**6.3.7. Determine the spectrum of infrastructure-sustainment activities that the U.S. military and other government entities may be able to support during a pandemic, contingent upon primary mission requirements, and develop mechanisms to activate them.**

6.3.7.1. HHS, in coordination with DHS, DOD, VA, and DOT, and as the lead for ESF #8, shall identify public health and medical capabilities required to support a pandemic response and work with other supporting agencies to identify and deploy or otherwise deliver the required capability or asset, if available. Measure of performance: inventory of public health and medical capabilities within 6 months; available public health or medical capabilities or assets deployed or delivered during a pandemic.

6.3.7.2. DOD and VA assets and capabilities shall be postured to provide care for military personnel and eligible civilians, contractors, dependants, other beneficiaries, and veterans and shall be prepared to augment the medical response of State, territorial, tribal, or local governments and other Federal agencies consistent with their ESF #8 support roles, within 3 months. Measure of performance: DOD and VA pandemic preparedness plans developed; in a pandemic, adequate health response provided to military and associated personnel.

6.3.7.3. VA shall develop draft emergency policies and directives allowing VA personnel and resources to be used for the treatment of non-veteran patients with pandemic influenza within 3 months. Measure of performance: emergency policies and directives drafted.

6.3.7.4. VA shall develop, test, and implement protocols and policies allowing VA personnel and resources to be used for the treatment of non-veteran patients during health emergencies, within 3 months. Measure of performance: protocols and policies developed and implemented.

- 6.3.7.5. DOD shall develop and implement guidelines defining conditions under which Reserve Component medical personnel providing health care in non-military health care facilities should be mobilized and deployed, within 18 months. Measure of performance: guidelines developed and implemented.

***d. Ensuring Effective Risk Communication***

- 6.3.8. Ensure that timely, clear, coordinated messages are delivered to the American public from authoritative sources at all levels of government and assist the governments of affected nations to do the same.**

- 6.3.8.1. HHS, in coordination with DHS, DOD, and VA, shall develop and disseminate a risk communication strategy within 6 months, updating it as required. Measure of performance: implementation of risk communication strategy on **www.pandemicflu.gov** and elsewhere.
- 6.3.8.2. DOD and VA, in coordination with HHS, shall develop and disseminate educational materials, coordinated with and complementary to messages developed by HHS but tailored for their respective departments, within 6 months. Measure of performance: up-to-date risk communication material published on DOD and VA pandemic influenza websites, HHS website **www.pandemicflu.gov**, and in other venues.



## CHAPTER 7 — PROTECTING ANIMAL HEALTH

### Introduction

Influenza viruses that cause severe disease outbreaks in animals, especially birds, are believed to be a likely source for the emergence of a human pandemic influenza virus. The avian influenza type A “H5N1” virus currently found in parts of Asia, Europe, and Africa is one of particular concern due to its demonstrated ability to infect both birds and mammals, including humans. Whether or not this H5N1 virus develops the ability to transmit efficiently between humans and cause a human pandemic, there will inevitably be other influenza viruses in animals that will pose such a threat in the future.

Most influenza viruses found in birds and other animals do not pose any threat to humans, but a few may have the potential to become a human pandemic strain and must be eradicated or otherwise controlled when they occur. Although there is no definitive way to identify all influenza viruses in animals that may have human pandemic potential, such potential could be evidenced by the ability of a virus that infects birds or other animals to also cause illness in humans or to cause illness in both birds and other animals.

Influenza viruses that cause severe illness and death in birds or other animals are known as “highly pathogenic” for the species in which that illness occurs. Some avian influenza viruses, such as the H5N1 in Asia, Europe, and Africa, cause high mortality in chickens and are referred to as highly pathogenic avian influenza (HPAI) viruses. Such avian viruses are generally of the H5 or H7 type, although not all H5 and H7 viruses are highly pathogenic for chickens. However, all H5 and H7 types have the potential to mutate into a highly pathogenic strain. In order to protect poultry and other birds in the United States, and also minimize or eliminate the possibility that a human pandemic strain might emerge from such viruses, all HPAI viruses or other H5 or H7 avian influenza viruses that infect domestic poultry in the United States will be eradicated or otherwise controlled. Because H5 and H7 types are not the only influenza A viruses that may have the potential to emerge as a human pandemic strain, other type A influenza viruses in animals that show evidence of human pandemic potential will also be eradicated or otherwise controlled.

Until a human pandemic influenza virus emerges, there is no way to know whether that virus will be able to infect and be transmitted by birds or other animals, or if it will “only” be transmissible from human-to-human. While it is possible that a human pandemic strain of influenza virus could infect and be transmitted by birds or other animals, it is probably unlikely.<sup>18</sup> In any case, if a human pandemic strain emerges, it will be very important to confirm through experimental and epidemiologic studies whether or not the virus can also infect, and be transmitted by, birds or other animals, so that any measures needed to mitigate the threat to humans and the impacts on poultry or other animals can be implemented.

A human pandemic influenza virus could emerge outside the United States or within our borders. Because of the potential for the HPAI H5N1 virus to become a pandemic strain, many international animal health initiatives are currently underway through the U.S. Agency for International Development

<sup>18</sup>It cannot be known what specific characteristics a human pandemic influenza virus will possess, but the virus will have to be able to efficiently bind to the receptors of, and replicate in, human respiratory cells, in order to be transmitted efficiently from human-to-human. Such a virus would not likely also

be able to efficiently bind to cell receptors and replicate efficiently in avian hosts, due to differences in receptor specificity and other species-specific factors. A slightly greater, but still low, likelihood may exist for a virus adapted to humans to also replicate in swine.

and the International Partnership on Avian and Pandemic Influenza to assist affected countries with control of the current outbreak. Many more international activities are planned (see Chapter 4 - International Efforts). The more that can be done through these efforts to address fundamental issues related to the detection and control of viruses with pandemic potential in birds or other animals, the lower the risk will be for the emergence of a human pandemic strain.

Regardless of where the risk for emergence exists, we must be prepared to respond appropriately. If an influenza virus with human pandemic potential is introduced into domestic birds or other animals in the United States, despite all international efforts to prevent it, we must detect and eradicate the virus as quickly as possible. If it is found in wild birds, efforts will be directed at preventing introduction into domestic birds or other susceptible animals, rather than eradication.

## **Key Considerations**

The Department of Agriculture (USDA) has a history of success in working with Federal partners, State, local, and tribal entities, and the poultry industry to eradicate avian influenza viruses, including HPAI and H5 or H7 viruses with the potential to become HPAI, that have been introduced into U.S. poultry. Significant outbreaks of HPAI or potential HPAI in poultry were eradicated in 1984 and 2002, as was a smaller outbreak in 2004.

Although such eradication efforts may help to protect human health, they can result in significant costs due to poultry production losses from bird depopulation activities and from quarantine or other movement restrictions placed on birds. But eradication of these viruses also protects the production of U.S. poultry, worth almost \$29 billion in 2004, including broiler production worth more than \$20 billion. The United States is the second largest exporter of poultry meat in the world and our trading partners are not only concerned about HPAI, but also increasingly wary of importing poultry or poultry products from any country that may have avian influenza viruses with the potential to become highly pathogenic.

The economic consequences of an HPAI outbreak in the United States would depend on its size, location, and type, and on the amount of time necessary to eradicate the outbreak. Production losses would depend on the proximity of the outbreak to major poultry areas, but with limited backyard flocks and strong biosecurity in large facilities, any outbreak would likely be contained with only modest production losses. The most economically significant recent outbreak of avian influenza in the United States occurred in 1983 and 1984, primarily in Pennsylvania and Virginia. That outbreak affected mainly layer flocks and resulted in the depopulation of 17 million birds and destruction of 14 million eggs. While the amount of birds and eggs destroyed was small relative to total annual U.S. production, the loss of breeder and laying flocks had a greater impact than implied by the destruction of the birds and eggs since they represent future production. Losses were estimated at \$65 million.

Unlike domestic birds, wild bird species are highly dispersed, highly mobile, and occupy a wide range of native habitats. These characteristics render any effort to eradicate avian influenza in wild bird populations impractical. The Department of the Interior (DOI), which is responsible for managing wild migratory birds under Federal law and international treaty, works closely with State wildlife agencies, other Federal agencies, and partners to conserve wild migratory bird populations through the management of habitats, regulation of sport hunting, and other management actions. The DOI maintains an intensive research and data management capability that allows it to track the movement of birds during the migration season, identify migratory stopover sites, and inform its partners of migratory bird arrivals.

USDA and DOI share the responsibility for managing the consequences of wildlife disease. USDA has the lead role in preventing the introduction of disease from wildlife to domestic birds and conducts a broad range of disease research, surveillance, and management activities associated with this role. DOI has the lead role in managing healthy wildlife populations for the benefit of the American public and conducts comprehensive field and laboratory wildlife disease investigations and disease research with emphasis on the ecology of disease and its impact on wild populations, surveillance, and management. The USDA and DOI programs complement one another such that the full range of management needs resulting from wildlife disease is addressed. Should H5N1 or any other HPAI virus be detected in wild birds, the departments will work together on a unified response, to include conducting additional surveillance of wild birds and recommending biosecurity measures to prevent interactions between domestic and wild birds.

### **Response Planning**

To respond effectively to an introduction of influenza in birds or other animals in the United States, Federal and State/tribal-level response plans and resources must be in place. Once in place, plans should regularly be updated at the Federal, State, tribal, and animal industry sector levels, and exercised among those levels. Emergency management roles must be clearly defined and understood at all levels. The *National Response Plan* (NRP) and the National Incident Management System (NIMS) provide a response structure, but response plans for disease outbreaks in animals must be exercised between all levels so that roles and functions are clearly understood prior to a response.

### **Communicating and Mitigating Risks**

There will be a need for timely and clear communication about the risks associated with the introduction of influenza and how to mitigate them, especially at the level of the individual producer or animal owner. Significant misconceptions may exist about risks, and accurate and open communication will be crucial in correcting any misconceptions. Owners and producers of birds or other animals at risk for influenza must understand their critical role in protecting those animals from infection and in reporting any illness that may indicate the presence of a pathogenic influenza virus. Similarly, State and tribal wildlife management authorities must understand their roles in identifying and reporting illness in wild animals that may presage the emergence of highly pathogenic influenza.

USDA currently conducts a multilevel outreach and education campaign called “Biosecurity for the Birds” to provide disease and biosecurity information to poultry producers, especially those with “backyard” production. The information provides guidance to bird owners and producers on preventing introduction of disease and mitigating spread of disease should it be introduced. The campaign also encourages producers to report sick birds, thereby increasing surveillance opportunities for avian influenza.

Animal industry groups should develop industry-specific standards for biosecurity and plans for outbreak response. Standards and plans should be as specific as required to deal with a highly contagious disease like influenza, but in particular need to address issues related to the zoonotic potential of an influenza outbreak. Response plans also need to help ensure successful eradication of the disease, yet preserve as much continuity of normal animal production activities as possible before, during, and after the outbreak. This kind of planning will require collaboration with Federal, State, local, and tribal entities to address issues that might otherwise negatively impact animal production during a disease response.

DOI conducts outreach to Federal, State, and tribal wildlife authorities, and the public through a multifaceted program of technical products related to wildlife disease. Through a series of bulletins, websites,

and other means, the DOI alerts and advises those who may come into contact with infected wildlife. Using this advice, State and tribal wildlife agencies should develop specific standards for biosecurity and plans for outbreak response. These plans need to address conditions specific to wildlife populations.

Animal outbreaks caused by influenza viruses with human pandemic potential, including those known to cause human illness, present challenges for preparedness and response due to the zoonotic potential of such viruses and the resulting risk for infection and illness in persons exposed to infected animals, carcasses, or animal waste. Mitigation of these risks requires specific planning, including working with public health and occupational health and safety professionals to determine requirements for personal protective equipment (PPE), seasonal influenza vaccination, and/or antiviral prophylaxis for personnel performing response functions with potential exposure to virus. Plans also need to address the logistical requirements for providing the necessary worker protection and the safe disposal of animal carcasses and animal waste.

### **Resources for a Response**

Potentially large quantities of response materiel will need to be distributed expeditiously and accurately. As prescribed in Homeland Security Presidential Directive 9, USDA has established a National Veterinary Stockpile (NVS) that can be rapidly distributed in the event of an animal disease outbreak. The NVS has a variety of materiel that would be necessary for a response to an influenza outbreak, including PPE, disinfectant, diagnostic reagents, and antiviral medication (for responders). In addition to the NVS materiel, there are currently 40 million doses of avian influenza vaccine available for use in poultry, should an outbreak occur. Half these doses are for an H5 virus and half are for an H7 virus. However, in the event of a large scale outbreak of avian influenza, additional stockpiles of avian influenza vaccine may be needed. In addition to vaccines, there will be a need for diagnostic reagents, equipment, and other materiel to be available for rapid deployment to the site(s) of an influenza outbreak in animals, especially in poultry or other birds.

### **Research and Development**

Perhaps even more important than having the planning, communication, and response resources in place, is ensuring that we have the scientific knowledge and tools necessary to detect and respond to an influenza outbreak in animals. Research and development will play a vital role in our preparedness to protect animals against influenza infection, detect infections when they occur, and respond effectively to influenza outbreaks caused by viruses with human pandemic potential. Enhancement of our knowledge of the ecology of influenza viruses, viral evolution, novel influenza strains that emerge in animals, and the determinants of virulence of influenza viruses in animal populations is essential. Better tools are needed for detection of influenza viruses in the environment, for providing immunity to avian populations, and for validating disease response strategies. All of this will require an appropriate infrastructure for animal health research and development. Most critically, there must be an adequate amount of laboratory research space that meets biosafety requirements appropriate for conducting animal studies using an influenza virus with pandemic potential. Deficiencies in research facility capacity will limit development of science-based solutions for the prevention, management, and control or eradication of influenza in animal populations.

### **Rapid Detection**

Although a human influenza pandemic may emerge outside the United States, early detection of influenza viruses with pandemic potential in animals within the United States is critical to minimizing

the chances of a human pandemic strain emerging here. A robust surveillance system in domestic animals and wildlife is required to ensure detection. Such surveillance of animals needs to integrate with human influenza surveillance activities at a national level. It is important for results of animal surveillance to serve as an input that may help target human surveillance efforts, relative to temporal, geographic, or other risk factors, especially if an influenza virus with human pandemic potential is detected in birds or other animals in the United States.

An extensive amount of influenza surveillance is currently conducted in poultry and wild birds in the United States. Commercial poultry operations are monitored for avian influenza through the National Poultry Improvement Plan (NPIP), and birds moving through the U.S. live bird marketing system (LBMS) are also tested for avian influenza. Wild birds are examined for avian influenza viruses through efforts involving the DOI, USDA, State wildlife authorities, and universities. Surveys of waterfowl and shore birds have been conducted in Alaska since 1998 looking for the presence of avian influenza viruses. Diagnostic testing of samples from these domestic and wild birds is carried out by many Federal, State, university, and private laboratories, including DOI's National Wildlife Health Center (NWHC) and USDA's National Veterinary Services Laboratories (NVSL) and Southeast Poultry Research Laboratory.

In addition to surveillance performed specifically to detect avian influenza in domestic and wild birds, the USDA employs specially trained wildlife disease biologists to survey for wildlife diseases and respond to disease outbreaks through its National Wildlife Disease Surveillance and Emergency Response System. This system ensures support to existing programs with appropriate sample collection, information exchange, and additional laboratory infrastructure. The USDA and State animal health authorities also employ specially trained veterinarians, called foreign animal disease diagnosticians, to investigate suspected cases of exotic disease in poultry and other influenza-susceptible species that are reported from USDA-accredited veterinary practitioners and from animal owners. Veterinary practitioners also submit specimens from sick birds and other influenza-susceptible species to State and university veterinary diagnostic laboratories, almost 40 of which have the capability to perform a rapid screening test for HPAI viruses as part of the National Animal Health Laboratory Network (NAHLN), a cooperative effort between USDA and the American Association of Veterinary Laboratory Diagnosticians.

Although substantial surveillance activities are already in place in the United States to detect avian influenza viruses with human pandemic potential in domestic poultry, enhancing surveillance in domestic animals (including at slaughter and processing) and wildlife will help ensure that reporting of these events will occur as early as possible. Animal populations that are most critical for additional surveillance activities are poultry and wild birds, not only in terms of increased numbers tested but also in the geographic distribution of testing to increase the probability of detection. In particular, domestic birds moving through the LBMS, farmed waterfowl and game birds, and migratory waterfowl and shore birds are important targets for increased avian influenza testing. Concomitant with increased targeting for animal sampling is the need for an increased capability to perform the necessary diagnostic testing to detect influenza viruses in those samples. Specifically, there is a need to enhance the capabilities of diagnostic laboratories participating in avian influenza surveillance of wild birds, and of commercial birds in the LBMS and in the NPIP, to be equivalent to those of laboratories in the NAHLN.

To fully utilize data collected as part of the national surveillance for influenza viruses with pandemic potential in animal populations, capabilities for capturing, analyzing, and sharing data must be in place. A database is needed to provide a means for evaluating the types of surveillance that should be conducted in the future, where the surveillance is needed, and the numbers of samples that must be collected. Such a database will also facilitate sharing of critical information with other animal health and



public health partners working to detect influenza viruses, especially those viruses that may have human pandemic potential.

### **Coordinated Response**

Detection of an outbreak of avian or other influenza virus with human pandemic potential in an animal population in the United States will demand a rapid and coordinated response by Federal, State, and tribal entities, industry partners, and other stakeholders. Initially there will be a State, local, and/or tribal response supported by USDA (for domestic animals) or both USDA and DOI (for wildlife). If the scope of the outbreak is beyond the immediate resource capabilities of USDA/DOI and the animal health officials in an affected State or tribal entity, USDA can implement an integrated Federal, State, tribal, and local response utilizing all necessary Federal resources under the NRP and Emergency Support Function #11 - Agriculture and Natural Resources (ESF #11). USDA is the coordinator of ESF #11 for an animal disease response, with DOI serving as the primary agency responsible for issues related to the protection of natural and cultural resources, including wildlife, endangered species, and migratory birds. Because of the general zoonotic potential of influenza outbreaks in birds or other animals, USDA will work closely with the Department of Health and Human Services (HHS), the coordinator of Emergency Support Function #8 - Public Health and Medical Services (ESF #8). Outbreaks known to have both human and animal infections will be investigated jointly by public health authorities, including HHS, and animal health authorities, including USDA, that will then work together to implement appropriate response strategies.

The response will be organized using the Incident Command System as prescribed by the NIMS. Depending on the circumstances of the outbreak and the animal population involved, the Secretary of Agriculture may declare an “extraordinary emergency” to enhance the response authorities of the USDA. If necessary, USDA would make a request to the Department of Homeland Security (DHS) for declaration of an Incident of National Significance that would invoke the full support of NRP coordination mechanisms. If the outbreak becomes extremely large, there will be a need to utilize all potential sources of support. To meet the demand for skilled responders, it may be necessary to have licensed veterinary practitioners cross jurisdictional boundaries, either State or national, to assist in the response. These boundaries can present barriers to veterinarians wishing to work as responders in any jurisdiction where they are not already licensed to practice.

### **Goals**

Overall, the goals for protecting animals against influenza viruses with human pandemic potential (or against a human pandemic virus, should it be able to infect animals) include: developing new capabilities in influenza preparedness, prevention, detection, and response; planning and preparedness for response to an outbreak; detecting influenza infections in animals, especially poultry and wild birds; and eradicating or controlling influenza outbreaks in animals that present a risk to human or animal health.

## Roles and Responsibilities

The responsibility for preparing for, detecting, and responding to influenza infections in birds or other animals, domestic or wild, is shared by everyone associated with the animals at risk. This includes animal owners, animal industry groups, State, local, and tribal wildlife management and animal health authorities, and the Federal Government. All these individuals and entities have important and interdependent roles in animal health-related activities.

### The Federal Government

The Federal Government will use all capabilities within its authority to support the private sector and State, local, and tribal animal health authorities in preparedness, surveillance, and response activities related to animal disease outbreaks. It will increase readiness to sustain essential Federal animal health functions during a human pandemic and provide animal health support services under the NRP.

**Department of Agriculture:** USDA is responsible for protecting American livestock, including poultry, from exotic or foreign animal diseases, such as HPAI. It advises individuals, the private sector, and State, local, and tribal entities, on appropriate biosecurity measures both before and after a disease is introduced, and helps to develop, support, and carry out surveillance for disease agents of concern. USDA provides diagnostic reference services and primary testing support, both prior to an outbreak and during an outbreak response. USDA stockpiles vaccines for possible use in a response to an outbreak of influenza with human pandemic potential in animals, and sponsors research on influenza viruses with pandemic potential and on vaccines that might be effective in controlling them. It provides assistance to the private sector and State, local, and tribal entities, in the development of influenza preparedness and response plans. Under the NRP, DHS has overall incident management coordination responsibilities and USDA will be the coordinator for ESF #11 for the response to a highly contagious disease like influenza, implementing an integrated national-level response with industry, State, local, and tribal responders. It provides response personnel, materiel, technical expertise, and funding for certain disease control and eradication activities. USDA is also responsible for providing Federal leadership to Federal, State, and tribal entities in managing problems caused by nuisance wildlife, including native wildlife, invasive species, and exotic animals. USDA partners with the DOI and others to coordinate the Federal Government's surveillance strategy for the early detection of HPAI in wild migratory birds and other wildlife when appropriate. USDA administers a National Wildlife Disease Surveillance and Emergency Response Program that is responsible for conducting daily surveillance on wildlife diseases, such as HPAI, and responding to a variety of emergencies including natural disasters and disease outbreaks. USDA also inspects and monitors meat, poultry, and egg products sold in interstate and foreign commerce to ensure products for public consumption are inspected for signs of disease.

**Department of the Interior:** DOI is responsible for managing and protecting certain wildlife, including migratory birds, under various laws and treaties and for protecting public health on more than 500 million acres of Federal land across the country. DOI coordinates the Federal Government's surveillance of wild migratory birds for the presence of HPAI virus, coordinates Federal surveillance with related surveillance activities of State, fish, and wildlife agencies, and provides leadership and support in the area of wildlife disease research and diagnostics to Federal and State natural resource agencies. DOI's NWHC works with department bureaus, as well as State, tribal, and other Federal entities, on wildlife disease investigations, providing the best available science and technical support for issues related to wildlife health and disease. This biosafety level 3 laboratory is actively involved in targeted surveillance of migratory birds and shorebirds, as well as wildlife morbidity and mortality event investigations to identify

causative agents of wildlife disease. In the event of an HPAI outbreak in wild migratory birds, DOI will work with Federal and State natural resource, agricultural health, and public health agencies to support timely and effective response.

**Department of Health and Human Services:** HHS's primary responsibilities are those actions required to protect the health of all Americans, including communication of information related to pandemic influenza, leading international and domestic efforts in surveillance and detection of influenza outbreaks, ensuring the provision of essential human services, implementing measures to limit spread, and providing recommendations related to the use, distribution, and allocation of countermeasures and to the provision of care in mass casualty settings. HHS supports research, education, and prevention projects addressing the Nation's pressing agricultural health and safety problems, evaluating agricultural injury and disease prevention, and developing and evaluating control technologies to prevent illness and injuries among agricultural workers and their families. Through its Centers for Agricultural Disease and Injury Research, Education, and Prevention program, HHS supports consultation and/or training to researchers, health and safety professionals, graduate/professional students, and agricultural extension agents and others in a position to improve the health and safety of agricultural workers.

**Department of Homeland Security:** While DHS has overall incident management coordination responsibilities, it is also a support agency to USDA under ESF #11 - Agriculture and National Resources. Under this annex, DHS may provide additional support in interdicting adulterated products in transport and at ports of entry; subject-matter expertise and technical assistance (e.g., Customs and Border Protection Agricultural Specialists); and air and transport services (e.g., U.S. Coast Guard), as needed, for personnel and laboratory samples. DHS's Homeland Security Operations Center will also receive updates from USDA. In the event of a zoonotic disease outbreak, DHS will coordinate with USDA and HHS to release public information.

**Department of Defense:** In the event that an animal health emergency exceeds the capability of civil authorities, the Department of Defense (DOD) may provide defense support of civil authorities in accordance with the NRP and appropriate DOD Directives, as well as other procedures and authorities that exist for requesting assistance from DOD. If authorized by the Secretary of Defense, DOD can provide personnel, equipment, facilities, materials, and pharmaceuticals to the extent that national security readiness is not compromised. USDA may request and receive support from DOD in the event that the presence of animal/plant diseases and/or pests, endemic or exotic, constitutes an actual or potential emergency. For the purposes of this plan, an emergency is defined as any sudden negative economic impact, either perceived or real, such as a "foreign animal disease" event or a natural disaster that threatens the viability of U.S. animal agriculture and thereby the food supply of the United States.

### **State, Local, and Tribal Entities**

State, local, and tribal entities are primarily responsible for detecting and responding to disease outbreaks and implementing measures to minimize the consequences of an outbreak. State, local, and tribal entities should have preparedness plans that address key issues in dealing with a disease outbreak in animals. They will be the first line of defense in limiting the spread of disease. Appropriate movement controls for susceptible birds or other animals and their products, and the ability to implement those controls, will be essential. For that purpose, there may be a need to integrate State, local, and tribal law enforcement entities into an animal disease response plan. Reporting mechanisms for use in early identification of suspect cases of influenza in animal populations should be established, as should mechanisms for communicating with the local animal agriculture community about influenza and response activities.



## The Private Sector and Critical Infrastructure Entities

The private sector plays an integral role in preparedness for, and successful response to, an animal disease outbreak. Animal industry groups should develop standards for biosecurity and plans for outbreak response that help ensure successful eradication of the disease yet preserve as much continuity of normal animal production activities as possible during the outbreak.

## Individuals and Families

Animal owners should practice appropriate biosecurity to prevent or minimize the risk of disease introduction prior to an outbreak, and must comply with quarantines or other movement restrictions to prevent or minimize the spread of disease during an outbreak.

## Actions and Expectations

### 7.1. Pillar One: Preparedness and Communication

To help ensure that response plans can be successfully implemented, a capability must exist to rapidly provide personnel for response activities and surge capacity for veterinary diagnostic laboratories. If an influenza outbreak occurs in animals, owners and producers of susceptible animals, as well as natural resource managers, must understand their role, and the role of Federal, State, and tribal entities, in responding to an influenza outbreak in domestic animals or wildlife and limiting spread of the disease. Stockpiled materiel and vaccines need to be increased, and additional research and development is essential, including simulation modeling to refine disease mitigation strategies.

#### *a. Planning for a Pandemic*

##### **7.1.1. Support the development and exercising of avian and pandemic response plans.**

7.1.1.1. USDA, in coordination with DHS, HHS, DOD, and DOI, and in partnership with State and tribal entities, animal industry groups, and (as appropriate) the animal health authorities of Canada and Mexico, shall establish and exercise animal influenza response plans within 6 months. Measure of performance: plans in place at specified Federal agencies and exercised in collaboration with States believed to be at highest risk for an introduction into animals of an influenza virus with human pandemic potential.

##### **7.1.2. Continue to work with States, localities, and tribal entities to develop medical and veterinary surge capacity plans.**

7.1.2.1. USDA shall partner with State and tribal entities to establish, organize, train, and exercise incident management teams and a veterinary reserve corps within 12 months. Measure of performance: a veterinary reserve corps and incident management teams trained for each of the States believed to be at highest risk for an introduction into an animal population of an influenza virus with human pandemic potential.

7.1.2.2. USDA, in coordination with DOD, HHS, DHS, and DOI, shall partner with States and tribal entities to ensure sufficient veterinary diagnostic laboratory

surge capacity for response to an outbreak of avian or other influenza virus with human pandemic potential, within 6 months. Measure of performance: plans and necessary agreements to meet laboratory capacity needs for a worst case scenario influenza outbreak in animals validated by utilization in exercises.

***b. Communicating Expectations and Responsibilities***

**7.1.3. Provide guidance and support to poultry, swine, and related industries on their role in responding to an outbreak of avian influenza, including ensuring the protection of animal workers and initiating or strengthening public education campaigns to minimize the risks of infection from animal products.**

- 7.1.3.1. USDA, in coordination with DHS, shall develop, disseminate, and encourage adoption of best practices and recommendations for maintaining the biosecurity of animals, especially poultry and swine, against infection and spread of influenza viruses and for reporting suspected cases of influenza with human pandemic potential in animals to State or Federal authorities, within 4 months. Measure of performance: incorporation of best practices by industry.
- 7.1.3.2. USDA, in coordination with DHS, shall partner with State and tribal entities, and industry groups representing poultry and swine producers and processors, and other stakeholders, to define and exercise response roles and capabilities within 9 months. Measure of performance: exercises involving State or tribal entities, at least one poultry industry group, and one swine industry group, conducted and after action reports produced.
- 7.1.3.3. HHS, in coordination with USDA, DHS, and the Department of Labor (DOL), shall work with the poultry and swine industries to provide information regarding strategies to prevent avian and swine influenza infection among animal workers and producers, within 6 months. Measure of performance: guidelines developed and disseminated to poultry and swine industries.
- 7.1.3.4. USDA, in coordination with DOI, shall collaborate with DHS and other Federal partners, with State, local, and tribal partners, including State wildlife authorities, and with industry groups and other stakeholders, to develop guidelines to reduce the risk of transmission between domestic animals and wildlife during an animal influenza outbreak, within 6 months. Measure of performance: guidelines for various outbreak scenarios produced, disseminated, and incorporated by partners.
- 7.1.3.5. DOI, in coordination with USDA, shall work with other Federal, State, and tribal partners to develop appropriate response strategies for use in the event of an outbreak in wild birds, within 4 months. Measure of performance: coordinated response strategies in place that can rapidly be tailored to a specific outbreak scenario.

***c. Producing and Stockpiling Vaccines, Antiviral Medications, and Medical Material***

**7.1.4. Expand the domestic supply of avian influenza vaccine to control a domestic outbreak of avian influenza in bird populations.**

- 7.1.4.1. USDA shall augment the current stockpile of 40 million doses of avian influenza vaccine with an additional 70 million doses within 9 months. Measure of performance: avian influenza vaccine stockpiles increased to 110 million doses.
- 7.1.4.2. USDA shall stockpile diagnostic reagents, PPE, antiviral medication for protection of response personnel, and other response materiel within 9 months. Measure of performance: materiel pre-positioned for rapid delivery to areas where poultry or other animals are believed to be at highest risk for an introduction of an influenza virus with human pandemic potential.

***d. Advancing Scientific Knowledge and Accelerating Development***

**7.1.5. Ensure that there is maximal sharing of scientific information about influenza viruses between governments, scientific entities, and the private sector.**

- 7.1.5.1. USDA and DOI shall perform research to understand better how avian influenza viruses circulate and are transmitted in nature, in order to improve information on biosecurity distributed to local animal owners, producers, processors, markets, auctions, wholesalers, distributors, retailers, and dealers, as well as wildlife management agencies, rehabilitators, and zoos, within 18 months. Measure of performance: completed research studies provide new information, or validate current information, on the most useful biosecurity measures to be taken to effectively prevent introduction, and limit or prevent spread, of avian influenza viruses in domestic and captive animal populations.
- 7.1.5.2. USDA and DOI shall perform research to develop and validate tools that will facilitate environmental surveillance for avian influenza viruses, especially in wild birds, through the evaluation of feathers, feces, water, or nesting material, within 24 months. Measure of performance: new environmental surveillance tools researched and made available for use by Federal, State, tribal, university, and other entities performing avian influenza surveillance.
- 7.1.5.3. USDA shall sequence genomes of all available avian influenza viruses to provide diagnostic sequences, identify possible vaccine antigens, and provide potential information on viral evolution, relationships, and determinants of virulence within 12 months. Measure of performance: genomes of avian influenza viruses sequenced and submitted to GenBank, and information reported on potential diagnostic sequences and viral relationships.
- 7.1.5.4. USDA shall perform research to improve vaccines and mass immunization techniques for use against influenza in domestic birds within 36 months. Measure of performance: an effective avian influenza vaccine that can be delivered simultaneously to multiple birds ready for commercial development.
- 7.1.5.5. USDA, in coordination with DHS, shall identify any deficiencies relative to needs for Federal animal research facility capacity, including appropriate biosafety levels, for performing studies of avian, swine, and other animal influenza viruses with pandemic potential, and establish a plan of action to ensure that needed facilities will be available to carry out those studies, within 6 months. Measure

of performance: deficiencies in capacity of Federal animal research facilities identified and plans developed for addressing those needs.

- 7.1.5.6. USDA, in coordination with DHS, DOI, and DOD, shall partner with State and tribal authorities to refine disease mitigation strategies for avian influenza in poultry or other animals through outbreak simulation modeling, within 6 months. Measure of performance: simulation models produced and reports issued on the results of influenza outbreak scenario modeling.

## **7.2. Pillar Two: Surveillance and Detection**

Even with the large amount of surveillance and significant diagnostic capabilities currently targeted at detecting avian influenza, additional actions need to be taken to help ensure rapid detection of influenza in birds or other animals, bolster our diagnostic capabilities, and improve our ability to analyze and share surveillance data.

### ***a. Ensuring Rapid Reporting of Outbreaks***

#### **7.2.1. Expand our domestic livestock and wildlife surveillance activities to ensure early warning of the spread of an outbreak to our shores.**

- 7.2.1.1. DOI and USDA shall collaborate with State wildlife agencies, universities, and others to increase surveillance of wild birds, particularly migratory water birds and shore birds, in Alaska and other appropriate locations elsewhere in the United States and its territories, to detect influenza viruses with pandemic potential, including HPAI H5N1, and establish baseline data for wild birds, within 12 months. Measure of performance: reports detailing geographically appropriate wild bird samples collected and influenza virus testing results.
- 7.2.1.2. USDA and DOI shall collaborate to develop and distribute information to State and tribal entities on the detection, identification, and reporting of influenza viruses in wild bird populations, within 6 months. Measure of performance: information distributed and a report available describing the type, amount, and audiences for the information.
- 7.2.1.3. USDA shall work with State and tribal entities, and industry groups, to perform surveys of game birds and waterfowl raised in captivity, and implement surveillance of birds at auctions, swap meets, flea markets, and public exhibitions, within 12 months. Measure of performance: samples collected at 50 percent of the largest auctions, swap meets, flea markets, and public exhibitions held in at least five States or tribal entities believed to be at highest risk for an avian influenza introduction.
- 7.2.1.4. USDA shall work with State and tribal entities to provide additional personnel in additional locations to increase the number of facilities inspected and number of samples collected for avian influenza virus testing within the LBMS, within 12 months. Measure of performance: number of facilities inspected and sampled increased by 50 percent compared to previous year.

**7.2.2. Support the development and sustainment of sufficient U.S. and host nation laboratory capacity and diagnostic reagents in affected regions and domestically, to provide rapid confirmation of cases in animals or humans.**

- 7.2.2.1. USDA shall increase the capacity of the NVSL and the NAHLN to process influenza surveillance samples from commercial and LBMS sources, as well as wild birds, and develop and contract for the production of test reagents for distribution at no cost to collaborating State and industry laboratories within 12 months. Measure of performance: national capacity for laboratory testing increased by 100 percent compared to previous year and contracts for production of required avian influenza test reagents in place.
- 7.2.2.2. USDA shall partner with State and tribal entities to provide additional support for laboratory activities associated with NPIP surveillance for avian influenza within 12 months. Measure of performance: cooperative support agreements with States and tribal entities developed and implemented.
- 7.2.2.3. DOI and USDA shall increase the wild bird testing capacity of the NWHC and the National Wildlife Research Center, respectively, to process avian influenza samples from wild birds, within 12 months. Measure of performance: national wild bird testing capacity for avian influenza virus increased by 50 percent compared to previous year.

***b. Using Surveillance to Limit Spread***

**7.2.3. Expand and enhance mechanisms for screening and monitoring animals that may harbor viruses with pandemic potential.**

- 7.2.3.1. USDA shall develop an integrated database, or enhance existing databases, to support the national initiative for comprehensive surveillance for influenza viruses with pandemic potential in domestic animals using data collected from multiple sources, within 12 months. Measure of performance: functioning animal influenza surveillance database producing reports for a variety of queries and supporting multiple analyses of data.
- 7.2.3.2. DOI, in coordination with USDA, shall work with State and tribal entities, universities, and others to implement the Avian Influenza Data Clearinghouse developed by the NWHC to support the integrated surveillance program for influenza in wild birds within 12 months. Measure of performance: a functional wild bird influenza data clearinghouse utilized by multiple stakeholders.

**7.3. Pillar Three: Response and Containment**

If an outbreak of influenza occurs in birds or other animals in the United States it will be necessary to respond rapidly and in a coordinated manner with Federal, State, and tribal officials, industry partners, natural resource managers, and other stakeholders. The capability to utilize all possible Federal sources of wildlife management and veterinary response surge capacities will need to be in place. In order to prevent the outbreak from spreading, the movements of susceptible species of domestic animals and their products must be controlled or halted in the outbreak

“control area.” During an outbreak it will be essential to implement an effective communication strategy to keep stakeholders and the public informed of response activities and to clearly elucidate and put into perspective the risks and hazards that may exist and how to mitigate them.

***a. Containing Outbreaks***

**7.3.1. Provide guidance for States, localities, and industry on best practices to prevent the spread of avian influenza in commercial, domestic, and wild birds, and other animals.**

- 7.3.1.1. USDA, in coordination with DHS, HHS, DOI, and the Environmental Protection Agency, shall partner with State and tribal entities, animal industries, individual animal owners, and other affected stakeholders to eradicate any influenza outbreak in commercial or other domestic birds or domestic animals caused by a virus that has the potential to become a human pandemic strain, and to safely dispose of animal carcasses. Measure of performance: at least one incident management team from USDA on site within 24 hours of detection of such an outbreak.
- 7.3.1.2. USDA shall coordinate with DHS and other Federal, State, local, and tribal officials, animal industry, and other affected stakeholders during an outbreak in commercial or other domestic birds and animals to apply and enforce appropriate movement controls on animals and animal products to limit or prevent spread of influenza virus. Measure of performance: initial movement controls in place within 24 hours of detection of an outbreak.
- 7.3.1.3. USDA shall be prepared to provide near real-time technical information and policy guidance for State and tribal entities, animal industries, and individuals, on best practices to prevent the spread of avian influenza in commercial and other domestic birds and animals during an outbreak, within 4 months. Measure of performance: information and guidance distributed within 72 hours of confirmed outbreak and report available describing type and amount of information, and audiences to whom delivered.
- 7.3.1.4. DOI shall coordinate with Federal, State, local, and tribal officials to identify and apply appropriate measures to limit the spread of influenza virus should an outbreak occur in free-ranging wildlife populations. Measure of performance: initial control measures implemented within 24 hours of detection of an outbreak in free-ranging wildlife.

***b. Leveraging National Medical and Public Health Surge Capacity***

**7.3.2. Activate plans to distribute medical countermeasures, including non-medical equipment and other material, from the Strategic National Stockpile and other distribution centers to Federal, State, and local authorities.**

- 7.3.2.1. USDA shall activate plans to distribute veterinary medical countermeasures and materiel from the NVS to Federal, State, local, and tribal influenza outbreak responders within 24 hours of confirmation of an outbreak in animals of



influenza with human pandemic potential, within 9 months. Measure of performance: NVS materiel distributed within 24 hours of confirmation of an outbreak.

**7.3.3. Address barriers to flow of public health, medical, and veterinary personnel across State and local jurisdictions to meet local shortfalls in public health, medical, and veterinary capacity.**

7.3.3.1. USDA, in coordination with DOS, shall partner with appropriate international, Federal, State, and tribal authorities, and with veterinary medical associations, including the American Veterinary Medical Association, to reduce barriers that inhibit veterinary personnel from crossing State or national boundaries to work in an animal influenza outbreak response, within 9 months. Measure of performance: agreements or other arrangements in place to facilitate movement of veterinary practitioners across jurisdictional boundaries.

**7.3.4. Determine the spectrum of public health, medical, and veterinary surge capacity activities that the U.S. military and other government entities may be able to support during a pandemic, contingent upon primary mission requirements, and develop mechanisms to activate them.**

7.3.4.1. USDA shall assess the outbreak response surge capacity activities that other Federal partners, including the DOD, may be able to support during an outbreak of influenza in animals and ensure that mechanisms are in place to request such support, within 6 months. Measure of performance: written assessment completed and all necessary activation mechanisms in place.

***c. Ensuring Effective Risk Communication***

**7.3.5. Work with State and local governments to develop guidelines to assure the public of the safety of the food supply and mitigate the risk of exposure from wildlife.**

7.3.5.1. USDA, in coordination with DHS, DOI, and HHS, shall work with State, local, and tribal partners, industry groups, and other stakeholders to develop, clear and coordinated pre-scripted public messages that can later be tailored to the specifics of a given outbreak and delivered by trained spokespersons, within 3 months. Measure of performance: appropriate informational and risk mitigation messages developed prior to an outbreak, then shared with the public within 24 hours of an outbreak.

7.3.5.2. USDA and HHS, in coordination with DHS, State, local, and tribal partners, industry groups, and other stakeholders, shall develop guidelines to assure the public of the safety of the food supply during an outbreak of influenza in animals, within 6 months. Measure of performance: guidelines for various outbreak scenarios produced and shared with partners; within first 24 hours of an outbreak, appropriately updated guidelines on food safety shared with the public.



- 7.3.5.3. USDA, in coordination with DOI, shall collaborate in working with Federal partners, with State, local, and tribal partners, including State wildlife authorities, and with industry groups and other stakeholders, to update and distribute guidelines to reduce the risk of transmission between domestic animals and wildlife and reduce the risk of spread to other wildlife species during an animal influenza outbreak. Measure of performance: guidelines updated and shared with the public within first 24 hours of an outbreak.

## CHAPTER 8 — LAW ENFORCEMENT, PUBLIC SAFETY, AND SECURITY

### Introduction

If a pandemic influenza outbreak occurs in the United States, it is essential that governmental entities at all levels continue to provide essential public safety services and maintain public order. It is critical that all stakeholders in State and local law enforcement and public safety agencies, whose primary responsibility this is, be fully prepared to support public health efforts and to address the additional challenges they may face during such an outbreak. Federal law enforcement and military officials should be prepared to assist in a lawful and appropriate manner, and all involved should be familiar with the established protocols for seeking such assistance and have validated plans to provide that assistance.

### Key Considerations

State, local, tribal, and private sector entities have primary responsibility for the public safety and security of persons and non-Federal property within their jurisdictions, and are typically the first line of response and support in these functional areas. However, the unique challenges that might confront State, local, tribal, and private sector entities could require them to request additional assistance, either of a logistical or operational nature, from within their States, from other States pursuant to a mutual aid compact, or from the Federal Government. Civil disturbances and breakdowns in public order might occur in several different situations: as health care facilities are overwhelmed with those seeking care and treatment for themselves or family members; as persons vie for limited doses of vaccines and antiviral medications; as supply-chain disruptions cause shortages in basic necessities; as individuals attempt to leave areas where outbreaks have occurred or where containment measures are in place, and, potentially, in border communities if neighboring countries are impacted. 9-1-1 emergency call centers and public safety answering points may be overwhelmed with calls for assistance, including requests to transport influenza patients.

In addition to facing these challenges and dealing with the day-to-day situations they normally face, State, local, and tribal law enforcement agencies may be called upon to enforce movement restrictions or quarantines, thereby diverting resources from traditional law enforcement duties. To add to these challenges, law enforcement and public safety agencies can also expect to have their uniform and support ranks reduced significantly as a result of the pandemic, especially if they are not vaccinated.

It also essential to protect the health and safety of law enforcement and public safety and security workers to ensure these critical personnel can safely and effectively perform their assigned roles given these additional challenges.

### Response Planning

It is essential that as part of State, local, and tribal overall pandemic response planning, their respective law enforcement and public safety agencies formulate comprehensive response plans based on in-depth understanding of the salient facts regarding a potential influenza outbreak and the related issues. The plans should establish close coordination and communications protocols between law enforcement and public safety agencies and public health and medical officials. Responsible elected officials, emergency management officials, public health officials, and members of the law enforcement and emergency response communities should then undergo training related to the execution of their plans

and participate in exercises and other activities to ensure their ability to execute their plan if necessary. Such exercises will raise their awareness of the pertinent issues and initiate dialogue concerning issues such as interagency cooperation, incident command, and agency-specific roles and responsibilities during a pandemic influenza outbreak.

As part of the planning process, outreach and coordination should also be conducted with respect to private sector entities responsible for safeguarding and sustaining critical infrastructure during an outbreak. It is essential that the services provided by these entities continue without interruption and that those private sector personnel responsible for providing security develop plans to continue to provide security despite the effects pandemic influenza will have on their respective workforces and the understanding that the availability of local law enforcement resources to respond or otherwise assist may be limited.

While this chapter outlines the types of Federal assistance that can be provided when States, territories, and localities need assistance, especially direct law enforcement assistance, planning officials should note that the Federal Government's ability to provide such assistance across the United States will be limited due to the relatively small numbers of Federal law enforcement personnel available to assist as well as the effects the outbreak will have on the Federal Government workforce. The ability of military personnel will likewise depend on many factors including whether such support is feasible in light of other national defense functions being provided at the time, and the impact of the pandemic on military personnel.

### **Understanding the Legal Framework**

Because emergency management in public health emergencies will depend heavily on the effective use of relevant legal authorities, public health, law enforcement, and emergency management officials, and fire and EMS first responders will benefit from joint training on the legal authorities essential to effective response in public health emergencies *before* the emergency occurs. While significant progress has been made since the terrorist attacks on September 11, 2001, in establishing joint investigative protocols and linkages among the key components of public health, emergency management, law enforcement, and emergency response communities, an influenza pandemic will present new challenges, and it is important that all concerned understand their roles and the governing legal authorities so that they can coordinate their efforts under a complex set of Federal, State, tribal, and local laws. Federal, State, local, and tribal governments should review their legal authorities to respond to an influenza pandemic, identify needed changes in the law, and pursue legislative action as appropriate.

### **Sharing Ideas and Experiences**

To facilitate coordination and planning at all levels and to identify issues, key Federal, State, local, and tribal law enforcement and public safety officials should be brought together with subject matter experts, including those in the public health and medical community, to discuss the influenza preparedness and response issues they may face, including maintaining civil order and how to effectively implement and enforce a quarantine or other restrictive measures. The unique needs and challenges faced by departments and agencies of all sizes should be considered. Those with relevant experience dealing with actual incidents such as the Toronto SARS experience should also be consulted. Their findings should result in the publication of best practices and model protocols, which should then be disseminated to their colleagues and counterparts throughout the Nation.

### **Protecting Law Enforcement and Public Safety Personnel**

Ensuring the health and safety of law enforcement officers and others who may be called upon to respond in a pandemic influenza outbreak or any other public health emergency is critical. The law enforcement and public safety community should take appropriate protective measures to minimize their risk of infection, and selected personnel should be provided training to ensure they are knowledgeable about these measures. Law enforcement personnel should obtain immunizations or other prophylaxis in accordance with the priorities established for the circumstance in the event quantities are limited.

### **Continuity of Operations**

Agencies should have continuity plans to ensure essential services are provided if significant numbers of their employees become ill during the outbreak as well as if disruptions in other sectors they depend on occur. Ideally such plans should address issues such as the reassignment of personnel to perform critical functions, encouraging personnel to have plans to take care of their families while they are assigned to critical functions, and determining at what point it would be necessary to seek additional assistance.

### **Outside Assistance**

To prepare for the possibility that assistance from partners such as the National Guard may be required to supplement State or local law enforcement and public safety response agencies that are undermanned or overwhelmed, State and local officials should prepare in advance the processes and procedures for assessing the need for such forces and how they will be utilized in the event they are needed. Critical to this contingency is a clear understanding within the law enforcement and public safety community as to the processes that will be required to request such augmentation. Additionally, appropriate joint training should be provided as necessary to Guard forces and the potential supported agencies to ensure they are prepared for their possible missions. Once training has been completed, joint exercises between Guard units and law enforcement and other emergency responders would allow them to work through command and control and interoperability issues.

### **Conducting Training and Preparedness Exercises**

Once all law enforcement and public safety stakeholders have formulated their plans, they should engage in joint discussions, training, and exercises to ensure that plans at the Federal, State, tribal, and local levels are effectively integrated. These discussions should identify issues such as how the Incident Command System (ICS) will function during a pandemic influenza outbreak if there are requirements for a quarantine or other similar restrictive efforts to deal with an extraordinary situation. While most incidents are managed at the local level by a member of the fire or law enforcement community, it may well be that local officials choose to designate a public health official to coordinate their response. Regardless of who is in the lead, however, public health and medical officials should participate in training on ICS policies and procedures, since they will undoubtedly be key players in these incidents and it is likely that many of them will not have had prior experience or training in this area. All Hazard Incident Management Team training would also be beneficial as it would bring together law enforcement, fire and rescue, public health, public works, and other key personnel so that each discipline learns how to work together with other disciplines.

**Implementing Control Measures**

While a detailed discussion of quarantine and related containment measures that may be implemented in the event of a pandemic influenza outbreak are set forth in Chapter 6 of this Implementation Plan (Plan), a brief outline of those measures is warranted here. The main goal of these containment measures is to delay the spread of disease and resulting adverse effects. Once cases are observed in the United States, early cases may be isolated from others (in a hospital or elsewhere) and their contacts (who may have been exposed) could be asked to remain out of contact with others for a period of time (voluntary quarantine). Other social distancing measures may be recommended or mandated by communities. These measures could involve recommendations on limiting personal contact, work-at-home options, limits on public gatherings, and school closures.

Geographic quarantine (*cordon sanitaire*) is the isolation of localities with documented disease transmission from localities still free of infection. It has been used occasionally throughout history in efforts to contain serious epidemics. It is important to distinguish this from the quarantine of case contacts described above, where exposure to an infectious agent, but not infection per se, has been confirmed. Although it is very unlikely that public health professionals would recommend a geographic quarantine once influenza transmission is observed in different locations, State, local, and tribal entities should still consider plans to assist with the implementation of such a measure. Whether geographic quarantine would be implemented by public health officials to contain an outbreak of influenza with pandemic potential at its source will depend on a number of factors including both the feasibility of implementing the quarantine and the ability of authorities to provide for the needs of the quarantined population.

Planning for the enforcement of quarantine or other control measures at the local level will likewise require extensive advance planning among stakeholders. Procedures for requesting mutual aid from other State and local jurisdictions should be examined and updated as necessary. Difficult issues such as rules on the use of force to enforce quarantine if necessary and what to do with those who refuse to be quarantined should be settled as much as possible in advance of any quarantine implementation. Jurisdictions with international borders or international airports should coordinate in advance with Federal officials who may be required to quarantine persons arriving in the United States. States, local, and tribal entities may also seek Federal assistance in enforcing their own quarantines, so planning should also address the mechanism for doing so. Although it is quite unlikely to be used, quarantine of a geographic area will present especially unique challenges, as it will likely require close coordination between agencies from overlapping or adjacent jurisdictions.

**Readiness through Situational Awareness**

While law enforcement and public safety officials are not generally expected to play an active role in surveillance and detection, they should maintain close communication with public health, EMS, and fire rescue officials who will likely be more engaged in disease surveillance efforts. This will enable them to plan and prepare as needed. As the possibility of an outbreak grows they should continue to test response plans, policies, and procedures and update them as required to ensure a continuous state of preparedness. The Federal Bureau of Investigation (FBI) will closely monitor events through coordination with the Centers for Disease Control and Prevention (CDC) and take appropriate action in the event that it is suspected that there was deliberate human intervention in the spread of the pandemic.

**Law Enforcement Response During an Outbreak**

During the course of a pandemic influenza outbreak, State, local, and tribal law enforcement and public safety agencies will be conducting operations in accordance with their established plans and protocols. It is possible that the *National Response Plan* (NRP) will be activated and it is likely that State, local, and tribal operations will be coordinated through emergency operations centers. In the event that State and local authorities and tribal entities need additional law enforcement assistance, established procedures, as set forth below, must be followed to obtain such assistance.

*State, Local, and Tribal Law Enforcement*

In the event of a civil disturbance, including rioting or looting, State and local law enforcement will normally provide the first response pursuant to State and local law. Consistent with State law, the Governor may deploy National Guard as needed to prevent or respond to civil disturbances. Mutual aid agreements, such as Emergency Management Assistance Compacts, may also be used to obtain assistance from both within States and from neighboring States.

*Federal Law Enforcement*

Federal agencies with law enforcement capabilities may investigate and respond to Federal crimes and conduct security measures as a result of a domestic emergency.

*Emergency Federal Law Enforcement Assistance*

The Federal Government may assist a State in maintaining order at the request of a Governor when State and local resources are overwhelmed and not capable of an effective response. There are two primary ways the Federal Government can provide such assistance: (1) providing Federal law enforcement personnel; and (2) pursuant to exceptions to the Posse Comitatus Act, 18 U.S.C. § 1385, when civilian law enforcement resources are inadequate, by the President directing the Armed Forces to assist with civilian law enforcement functions.

When Federal departments and agencies are requested to provide public safety and security support, the assistance is provided through the mechanism of Emergency Support Function #13 – Public Safety and Security (ESF #13) of the NRP. ESF #13 provides Federal public safety and security assistance to support prevention, preparedness, response, and recovery priorities in circumstances where locally available resources are overwhelmed or are inadequate, or where a unique Federal capability is required.

*Civilian Federal Law Enforcement Assistance*

Under the Emergency Federal Law Enforcement Assistance Act, 42 U.S.C. § 10501 et seq., the Attorney General may provide law enforcement assistance, including Federal personnel, in response to a Governor's written request, when he determines that such assistance is necessary to provide an adequate response to a law enforcement emergency. The provisions define a law enforcement emergency as an uncommon situation requiring law enforcement resources that threatens to become of serious or epidemic proportions, and for which State and local resources are inadequate to protect lives or property, or to enforce criminal laws. To the extent Federal personnel would be used to enforce State or local law, they should be deputized or otherwise authorized under State or local law to exercise the key law enforcement powers (arrest, search, seizure) involved in enforcing those laws.



*Use of the Military for Law Enforcement Duties*

Although the primary mission of the Department of Defense (DOD) is the defense of the United States, the Department may, with approval of the Secretary of Defense, provide logistical support for law enforcement operations that does not involve the use of law enforcement powers such as arrest authority. In addition, in certain situations DOD personnel may be directed by the President -- traditionally only as a last resort and in support of civilian authorities -- to perform actual law enforcement responsibilities.

**The Law Enforcement Role in Containment**

Although as set forth above there are less-intrusive strategies for stopping the spread of disease, response to an influenza pandemic could require more restrictive measures such as isolation or quarantine and offer social distancing measures such as movement restrictions. Most States have broad quarantine authorities enacted pursuant to their police powers. The Federal Government also has statutory authority to order a quarantine to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States or from one State or possession into any other State or possession. “Influenza caused by novel or re-emergent influenza viruses that are causing, or have the potential to cause, a pandemic” is on the list of specified communicable diseases for which Federal quarantine is available.

*State Quarantine*

If necessary, State and local law enforcement agencies, with assistance from their State’s National Guard as needed, will normally enforce quarantines or other containment measures ordered by State or local authorities. Customs and Coast Guard officers may assist in enforcing State quarantines at the direction of the Secretary of Health and Human Services. At the request of State and local authorities, if authorized under the Emergency Law Enforcement Assistance Act, and with appropriate deputations under Federal, State, and local law, Federal law enforcement officers can assist in State and local quarantine enforcement. If directed by the President pursuant to the Insurrection Act, the military may suppress domestic unrest associated with resistance to a State quarantine.

*Federal Quarantine and Other Movement Restrictions*

**Borders:** The President has the authority to bar entry into the United States of aliens who have pandemic influenza if he determines that entry is detrimental to the interests of the United States. The Secretary of Health and Human Services may prohibit the entry of persons or property from foreign countries where the entry of such persons or property would present a serious danger of the introduction of a communicable disease. The Department of Homeland Security (DHS) has broad general authority pursuant to the customs and immigration laws to examine merchandise, cargo, conveyances, and persons upon their entry to the United States to ensure that imports comply with U.S. law, and to seize and forfeit vessels, animals, or other things used in the unlawful importation or transportation of articles contrary to U.S. law. Customs and Coast Guard officers are required to aid in the enforcement of Federal quarantine rules and regulations. Furthermore, Customs and Coast Guard officers and “military officers commanding in any fort or station upon the seacoast” are required to aid in the enforcement of State quarantines.

**Air and other Transportation modes:** The Federal Aviation Administration (FAA) can order United States flag air carriers not to enter designated airspace of a foreign country (e.g., to keep airspace clear for rescue operations). If FAA determines that an emergency exists related to safety in air commerce that



requires immediate action, FAA may prescribe regulations and issue orders immediately to meet that emergency. Likewise, the Transportation Security Administration (TSA) Assistant Secretary may issue regulations or security directives immediately to protect transportation security in all modes of transport.

**Rail:** Any movement in the United States by rail carrier (including commuter rail but excluding urban rapid transit not connected to the general system of rail transportation) may be stopped, redirected, or limited by the authority of the Surface Transportation Board (STB) or the Federal Railroad Administration (FRA), or both, irrespective of the commodity involved. FRA may issue an emergency order imposing any restrictions or prohibitions necessary to abate what FRA determines is an emergency situation involving a hazard of death or personal injury caused by unsafe conditions or practices.

#### *Persons Arriving From Foreign Countries and Traveling Between States*

Pursuant to regulation, the CDC may quarantine individuals arriving from foreign countries or possessions who are reasonably believed to be infected with or exposed to any of the communicable diseases specified by the President in an Executive Order. In addition, CDC may quarantine individuals reasonably believed to be infected with or exposed to such diseases and traveling from one State or possession into another.

## **Roles and Responsibilities**

### **The Federal Government**

Federal law enforcement officials are responsible for contingency planning relating to public safety and security missions in support of the Federal response to a pandemic. In particular, certain agencies are assigned specific security and other responsibilities in the NRP's ESF #13 and Emergency Support Function #8 - Public Health and Medical Services (ESF #8).

**Department of Justice:** The Attorney General, as the chief law enforcement officer of the United States, with appropriate coordination with other Federal officials, is responsible by law (42 U.S.C. § 10521), for determining whether to authorize Federal law enforcement assistance, upon the written request of a Governor, in the case of a law enforcement emergency for which State and local resources are inadequate to protect lives or property, or to enforce criminal laws. This is separate and distinct from the role the Attorney General has, in coordination with the Secretary of the Department of Homeland Security, under ESF #13, which provides a mechanism for coordinating and providing Federal-to-Federal support or Federal support to State and local authorities to include non-investigative/non-criminal law enforcement, public safety, and security capabilities and resources.

Designated Department of Justice (DOJ) officials, including those in the United States Marshals Service (USMS), may deputize Federal law enforcement personnel from other agencies as Special Deputy United States Marshals to broaden their law enforcement authorities.

The USMS serves as the lead Federal law enforcement security component for the Strategic National Stockpile (SNS). A Memorandum of Agreement between the Department of Health and Human Services (HHS) and DOJ details previously agreed-upon responsibilities that are to be fulfilled by the USMS during the movement and transition of SNS assets. The USMS also works with HHS in coordinating with State and local law enforcement officials concerning SNS future planning, exercises, and operations.

The FBI is responsible for monitoring the outbreak situation as it develops for any indications that it may not be the result of natural causes and upon learning of such information, taking the appropriate inves-

tigative action as well as notifying the DHS Homeland Security Operations Center and the National Counterterrorism Center as set forth in the Biological Incident Annex of the NRP.

Department of Homeland Security: Pursuant to the NRP, the Secretary of DHS will coordinate all Federal operations within the United States to prepare for, respond to, and recover from terrorist attacks, natural disasters, and other emergencies. The Secretary of DHS is designated by Homeland Security Presidential Directive 5 as the “principal Federal official” for domestic incident management. Additionally, DHS agencies with law enforcement components have authority and responsibility to take actions related to the Federal response to an influenza pandemic, and may exercise authority over certain modes of transportation.

DHS, in conjunction with DOJ, is the co-coordinator for ESF #13 of the NRP. As such, they coordinate preparedness activities with ESF #13 supporting agencies and ensure that all activities performed under the purview of ESF #13 are related to the safety and security of the public. Many of DHS’s operational elements also possess law enforcement capabilities that could be leveraged during a pandemic. For example, United States Secret Service, Customs and Border Protection, Immigration and Customs Enforcement, and TSA agents can assist State and local authorities with additional public safety and security requirements not only at ports of entry, but also in other locations, as required.

Department of Defense: DOD is responsible, at the direction of the President, for supplementing law enforcement resources with military personnel performing law enforcement functions. Such assistance ordinarily would be rendered only if civilian law enforcement agencies were overwhelmed and only if such assistance could be rendered without adversely affecting DOD’s ability to perform its primary mission of defending the United States. The assistance may be provided if the President invokes the Insurrection Act at the request of a State or on his own, suppressing domestic violence or enforcing Federal law. DOD is a support agency to ESF #13 and may also provide public safety and security assistance of a logistical or support nature under the concept of Defense Support of Civil Authorities, when approved and directed by the Secretary of Defense.

### **States, Local, and Tribal Entities**

State, local, and tribal law enforcement and public safety agencies have primary responsibility for providing public safety and security during a pandemic outbreak. These agencies are responsible for learning about the challenges they will face in a potential pandemic influenza outbreak and collaborating with the appropriate stakeholders in their respective jurisdictions. These stakeholders should include public health, judicial, fire service, corrections, and emergency management personnel. It is critical that these stakeholders develop comprehensive and mutually supporting plans that will enable them to continue their operations and respond to the challenges they will face in an outbreak.

The Adjutant General of each State, with guidance from DOD (including the National Guard Bureau) and assistance as appropriate for situations when State National Guard forces are either federalized or operating under a Title 32 status, are responsible for contingency planning and training to prepare Guard units within their State for public safety and security missions they may be assigned in a pandemic influenza outbreak.

## Actions and Expectations

### 8.1. Pillar One: Preparedness and Communication

#### *a. Planning for a Pandemic*

**8.1.1. Develop Federal implementation plans on law enforcement and public safety, to include all components of the Federal Government and to address the full range of consequences of a pandemic, including human and animal health, security, transportation, economic, trade, and infrastructure considerations. Ensure appropriate coordination with State, local, and tribal governments.**

- 8.1.1.1. States should ensure that pandemic response plans adequately address law enforcement and public safety preparedness across the range of response actions that may be implemented, and that these plans are integrated with authorities that may be exercised by Federal agencies and other State, local, and tribal governments.
- 8.1.1.2. DHS, in coordination with DOJ, HHS, DOL, and DOD, shall develop a pandemic influenza tabletop exercise for State, local, and tribal law enforcement/public safety officials that they can conduct in concert with public health and medical partners, and ensure it is distributed nationwide within 4 months. Measure of performance: percent of State, local, and tribal law enforcement/public safety agencies that have received the pandemic influenza tabletop exercise.
- 8.1.1.3. State, local, and tribal governments should review their legal authorities that may be needed to respond to an influenza pandemic, identify needed changes in the law, and pursue legislative action as appropriate.
- 8.1.1.4. DOJ shall ensure that appropriate Federal and State Court personnel are provided the information necessary to enable them to plan for the continuity of critical judicial functions during a pandemic. Measure of performance: this plan made available to all appropriate Federal and State court personnel.
- 8.1.1.5. States should ensure pandemic response plans address EMS, fire, public works, emergency management, and other emergency response and public safety preparedness.

**8.1.2. Continue to work with States, localities, and tribal entities to establish and exercise pandemic response plans.**

- 8.1.2.1. DOJ, in coordination with HHS, DOL, and DHS, shall convene a forum for selected Federal, State, local, and tribal law enforcement/public safety personnel to discuss the issues they will face in a pandemic influenza outbreak and then publish the results in the form of best practices and model protocols within 4 months. Measure of performance: best practices and model protocols published and distributed.

- 8.1.2.2. DOJ shall advise State Governors of the processes for obtaining emergency Federal law enforcement assistance, within 3 months. Measure of performance: all State Governors advised.
- 8.1.2.3. DOJ shall advise State Governors of the processes for requesting Federal military assistance under the Insurrection Act, within 3 months. DOD, after coordination with DOJ, shall publish updated policy guidance on Military Assistance during Civil Disturbances, within 6 months. Measure of performance: all State Governors advised and guidance published.
- 8.1.2.4. HHS and DOJ shall ensure consistency of the CDC Public Health Emergency Law Course with the *National Strategy for Pandemic Influenza (Strategy)*, this Plan and other Federal pandemic documents and then disseminate the CDC Public Health Emergency Law Course across the United States within 6 months. Measure of performance: distribution of presentations of reviewed public health emergency law course to all States.
- 8.1.2.5. DOD, in consultation with DOJ and the National Guard Bureau, and in coordination with the States as such training applies to support of State law enforcement, shall assess the training needs for National Guard forces in providing operational assistance to State law enforcement under either Federal (Title 10) or State (Title 32 or State Active Duty) in a pandemic influenza outbreak and provide appropriate training guidance to the States and Territories for units and personnel who will be tasked to provide this support, within 18 months. Measure of performance: guidance provided to all States.
- 8.1.2.6. DOD, in consultation with DOJ, shall advise State Governors of the procedures for requesting military equipment and facilities, training and maintenance support as authorized by 10 U.S.C. §§ 372-74, within 6 months. Measure of performance: all State Governors advised.
- 8.1.2.7. DHS, in coordination with DOJ, DOD, DOT, HHS, and other appropriate Federal Sector-Specific Agencies, shall convene a forum for selected Federal, State, local, and tribal personnel to discuss EMS, fire, emergency management, public works, and other emergency response issues they will face in a pandemic influenza outbreak and then publish the results in the form of best practices and model protocols within 4 months. Measure of performance: best practices and model protocols published and distributed.

***b. Communicating Expectations and Responsibilities***

**8.1.3. Provide guidance to individuals on infection control behaviors they should adopt pre-pandemic, and the specific actions they will need to take during a severe influenza season or pandemic, such as self-isolation and protection of others if they themselves contract influenza.**

- 8.1.3.1. HHS, in coordination with DOL, shall provide clear guidance to law enforcement and other emergency responders on recommended preventive measures,

including pre-pandemic vaccination, to be taken by law enforcement and emergency responders to minimize risk of infection from pandemic influenza, within 6 months. Measure of performance: development and dissemination of guidance for law enforcement and other emergency responders.

***c. Establishing Distribution Plans for Vaccines and Antiviral Medications***

**8.1.4. Develop credible countermeasure distribution mechanisms for vaccine and antiviral agents prior to and during a pandemic.**

- 8.1.4.1. State, local, and tribal law enforcement agencies should coordinate with appropriate medical facilities and countermeasure distribution centers in their jurisdictions (as recognized in Chapter 6, security at these facilities will be critical in the event of an outbreak) to coordinate security matters within 6 months.

**8.3. Pillar Three: Response and Containment**

***a. Containing Outbreaks***

**8.3.1. Encourage all levels of government, domestically and globally, to take appropriate and lawful action to contain an outbreak within the borders of their community, province, State, or nation.**

- 8.3.1.1. HHS, in coordination with DOJ, DOS, and DHS, shall determine when and how it will assist States in enforcing their quarantines and how it will enforce a Federal quarantine, within 9 months. Measure of performance: guidelines on quarantine enforcement available to all States.

***b. Sustaining Infrastructure, Essential Services, and the Economy***

**8.3.2. Determine the spectrum of infrastructure-sustainment activities that the U.S. military and other government entities may be able to support during a pandemic, contingent upon primary mission requirements, and develop mechanisms to activate them.**

- 8.3.2.1. DOJ, DHS, and DOD shall engage in contingency planning and related exercises to ensure they are prepared to maintain essential operations and conduct missions, as permitted by law, in support of quarantine enforcement and/or assist State, local, and tribal entities in law enforcement emergencies that may arise in the course of an outbreak, within 6 months. Measure of performance: completed plans (validated by exercise(s)) for supporting quarantine enforcement and/or law enforcement emergencies.
- 8.3.2.2. DHS, in coordination with DOJ, DOD, DOT, HHS, and other appropriate Federal Sector-Specific Agencies, shall engage in contingency planning and related exercises to ensure they are prepared to sustain EMS, fire, emergency management, public works, and other emergency response functions during a pandemic, within 6 months. Measure of performance: completed plans (validated by exercise(s)) for supporting EMS, fire, emergency management, public works, and other emergency response functions.

## CHAPTER 9 — INSTITUTIONS: PROTECTING PERSONNEL AND ENSURING CONTINUITY OF OPERATIONS

### Introduction

It is the policy of the United States to have in place a comprehensive and effective program to ensure survival of our constitutional form of government, the uninterrupted continuation of national-level essential functions under all circumstances, and the resumption of all government functions and activities quickly following any disruption. This policy is in effect for all hazards but will require specialized planning in the event of an influenza pandemic.

Continuity of operations (COOP) is defined as the activities of individual Federal departments and agencies and their sub-components to ensure that the capability exists to continue essential agency functions across a wide range of potential emergencies. The Federal Executive Branch provides guidance on effective continuity planning in *Federal Preparedness Circular — 65, Federal Executive Branch Continuity of Operations* (FPC-65) and for State and local continuity planners in *Interim Guidance on Continuity of Operations Planning for State and Local Governments*. COOP planning at the State and local government level mirrors Federal guidance to ensure the continuation of services to each level of government's communities and constituents. Similarly, most businesses engage in business continuity planning, which outlines a set of procedures that define how a business will sustain or recover its critical functions in the event of an unplanned disruption to normal business operations. Such planning for an influenza pandemic must recognize that the next pandemic may come in waves, each lasting weeks or months, and pass through communities of all sizes across the United States and around the world.

Unlike many other catastrophic events, an influenza pandemic will not directly affect the physical infrastructure of an organization. While a pandemic will not damage power lines, banks, or computer networks, it will ultimately threaten all critical infrastructure by its impact on an organization's human resources by removing essential personnel from the workplace for weeks or months. Employers should include considerations for protecting the health and safety of employees during a pandemic in their business continuity planning.

The Federal Government recommends that government entities and the private sector plan with the assumption that up to 40 percent of their staff may be absent for periods of about 2 weeks at the height of a pandemic wave with lower levels of staff absent for a few weeks on either side of the peak. These absences may be due to employees who: care for the ill; are under voluntary home quarantine due to an ill household member; care for children dismissed from school; feel safer at home; or are ill or incapacitated by the virus. Because the movement of essential personnel, goods and services, and the maintenance of critical infrastructure are necessary during an event that spans weeks to months in any given community, effective continuity planning including protection of personnel during an influenza pandemic is a "good business practice" that must become part of the fundamental mission of all Federal, State, local, and tribal governmental departments and agencies, private sector businesses and institutions, and schools and universities.



The private sector will play an integral role in a community response to pandemic influenza by protecting employees' and customers' health and safety, and mitigating impact to the economy and the functioning of society. Because the private sector also owns and maintains approximately 85 percent of the U.S. critical infrastructure, it is imperative that business continuity plans include procedures to mitigate the potential disruptions caused by an influenza pandemic.

Numerous activities can be conducted now to plan for the potential of a pandemic, while other activities will require a plan for action when more information is available. This chapter provides guidance for organizations engaged in developing and improving plans to prepare for and respond to an influenza pandemic. All governmental departments and agencies at the Federal, State, local, and tribal levels, private sector businesses, and academic institutions must ensure that the capability exists to continue essential functions in the event of a disruption to normal operations. A checklist of key planning activities to supplement existing all-hazards business continuity plans for public and private organizations and businesses, schools and universities, and faith-based and community organizations is provided in Appendix A. Further guidance and references for these activities can be found at [www.pandemicflu.gov](http://www.pandemicflu.gov).

## **Key Considerations**

### **Planning Requirements for Pandemic Influenza Continuity of Operations**

FPC-65 provides guidance on elements recognized across the Executive Branch as supportive of effective continuity planning. While the guidance in FPC-65 applies solely to the Federal Executive Branch, the planning elements that FPC-65 describes apply across all levels of government as well as the private sector and can be used to develop pandemic specific planning resources. Highlighted below are the 11 COOP program elements relevant to pandemic influenza planning.

#### *1. Plans and Procedures*

The foundation of a viable COOP program is the development and documentation of a COOP plan that, when implemented, will provide for the continued performance of an organization's essential functions under all circumstances. In order to reduce the pandemic threat, a portion of the COOP plan's objective should be to minimize the health, social, and economic impact of a pandemic on the United States.

#### *2. Essential Functions*

Essential functions are those functions that enable organizations to provide vital services, exercise civil authority, maintain the safety and well being of the general populace, and sustain the industrial/economic base in an emergency. During a pandemic, or any other emergency, these essential functions must be continued in order to facilitate emergency management and overall national recovery. Within the private sector, essential functions can be regarded as those core functions, services, and capabilities required to sustain business operations.

#### *3. Delegations of Authority*

Clearly pre-established delegations of authority are vital to ensuring that all organizational personnel know who has the authority to make key decisions in a COOP situation. Because absenteeism may reach a peak of 40 percent at the height of a pandemic wave, delegations of authority are critical.

#### *4. Orders of Succession*



An order of succession is essential to an organization's COOP plan to ensure personnel know who has authority and responsibility if the leadership is incapacitated or unavailable in a COOP situation. Since an influenza pandemic may affect regions of the United States differently in terms of timing, severity, and duration, businesses with geographically dispersed assets and personnel should consider dispersing their order of succession.

#### *5. Alternate Operating Facilities*

The identification and preparation of alternate operating facilities and the preparation of personnel for the possibility of an unannounced relocation of essential functions and COOP personnel to these facilities is part of COOP planning. Because a pandemic presents essentially simultaneous risk everywhere, the use of alternative operating facilities must be considered in a non-traditional way. COOP planning for pandemic influenza will involve alternatives to staff relocation/co-location such as social distancing in the workplace through telecommuting, or other means. In addition, relocation and redistribution of staff among alternative facilities may reduce the chance of infection impacting centralized critical operations staff simultaneously.

#### *6. Interoperable and Effective Communications*

The success of a viable COOP capability is dependent upon the identification, availability, and redundancy of critical communication systems to support connectivity of internal organizations, external partners, critical customers, and the public. Systems that facilitate communication in the absence of person-to-person contact can be used to minimize workplace risk for essential employees and can potentially be used to restrict workplace entry of people with influenza symptoms.

#### *7. Critical Business Records and Databases*

Businesses should identify, protect, and ensure the ready availability of electronic and hardcopy documents, references, records, and information systems needed to support essential functions. Pandemic influenza COOP planning must also identify and ensure the integrity of vital systems that require periodic maintenance or other direct physical intervention by employees.

#### *8. Human Capital*

Each organization must develop, update, exercise, and be able to implement comprehensive plans to protect its workforce. Although an influenza pandemic will not directly affect the physical infrastructure of an organization, a pandemic will ultimately threaten all operations by its impact on an organization's human resources. The health threat to personnel is the primary threat to continuity of operations during a pandemic.

#### *9. Testing, Training and Exercises*

Testing, training, and exercising of COOP capabilities are essential to assessing, demonstrating, and improving the ability of organizations to execute their COOP plans and programs during an emergency. Pandemic influenza COOP plans should test, train, and exercise sustainable social distancing techniques that reduce person-to-person interactions within the workplace.

### *10. Devolution of Control and Direction*

Devolution is the capability to transfer authority and responsibility for essential functions from an organization's primary operating staff and facilities, to other employees and facilities, and to sustain operational capability under devolved authority for an extended period. Because local outbreaks will occur at different times, have variable durations, and may vary in their severity, devolution planning may need to consider rotating operations between regional/field offices as a pandemic wave moves throughout the United States.

### *11. Reconstitution*

Reconstitution is the process by which an organization resumes normal operations. The objective during recovery and reconstitution after a pandemic is to expedite the return of normal services and operations as quickly as possible. Since a pandemic will not harm the physical infrastructure or facilities of an organization, and because long-term contamination of facilities is not a concern, the primary challenge for organizations after a pandemic will be the return to normal and bringing their systems back to full capacity. The mortality rate of a pandemic will depend on characteristics of the causative virus that cannot be predicted in advance, but for planning purposes it may be helpful to consider historical examples. The mortality rate of the 1918 pandemic in the United States — the worst influenza pandemic of the 20th century — is estimated to have been about 2 percent of those infected (about 0.5 percent of the total population). Using this historical information and current models of disease transmission, it is projected that a modern pandemic of equivalent lethality could lead to the deaths of 2 million people in the United States alone.

## **Continuity and Critical Infrastructure Protection**

Public and private sector entities depend on certain critical infrastructure for their continued operations. Homeland Security Presidential Directive 7 (HSPD-7) identifies 17 critical infrastructure and key resources vital to national functioning.<sup>19</sup> Recognizing that more than 85 percent of the critical infrastructure is owned and operated by the private sector, the development of public-private partnership is paramount to securing our Nation's assets.<sup>20</sup>

Critical infrastructure protection (CIP) entails all the activities directed at safeguarding indispensable people, systems (especially communications), and physical infrastructure associated with the operations of the 17 critical infrastructure sectors. However, sustaining the operations of critical infrastructure under conditions of pandemic influenza will depend largely on individual organizations' development and implementation of (1) plans for business continuity under conditions of staffing shortages; and (2) plans to protect the health of their workforces. This is also true for maintaining economic activity generally, above and beyond the question of critical infrastructure. General recommendations for both of

---

<sup>19</sup> HSPD-7 defines critical infrastructure to include the following sectors: agriculture and food; public health and health care; drinking water and water treatment systems; energy (including the production, refining, storage, and distribution of oil and gas, and electric power except for nuclear facilities); banking and finance; national monuments and icons; defense industrial base; information technology; telecommunications; chemical; transportation systems (including mass transit, aviation, maritime, ground/surface, and rail and pipeline systems); emergency services; and postal and shipping. HSPD-7 defines key resources to include: dams; government facilities; commercial facilities; and nuclear reactors, material, and waste.

---

<sup>20</sup> HSPD-7 and the Interim National Infrastructure Protection Plan define an architecture for the Federal Government to coordinate with representatives of these critical infrastructure and key resource sectors. The Federal Government will use this structure to develop sector-specific guidance and share information. Private sector-led Sector Coordinating Councils are being established to work with their appropriate Sector-Specific Agencies via Government Coordinating Councils, which represent the government agencies that have a role in protecting the respective sectors. Currently, the Department of Homeland Security's (DHS) Office of Infrastructure Protection is finalizing the National Infrastructure Protection Plan. This finalized document will refine the public-private partnership model and a process for protecting critical infrastructure.

these areas are provided in this chapter.

COOP is one of the basic goals of CIP. During a pandemic, all critical infrastructure sectors might not be affected to the same degree or at the same time. Although pandemic influenza would be expected to affect the workforce across all sectors, a pandemic's impact in terms of demand for services may disproportionately affect several sectors including transportation, health care, agriculture, and emergency services. Sector-specific guidance and recommendations regarding transportation systems, health care, animal health, and emergency services (including law enforcement) are provided in Chapters 5, 6, 7, and 8, respectively. Development of more refined sector-specific guidance in partnership with critical infrastructure owners and operators will require further action.

### **Business Continuity Under Conditions of Staffing Shortages**

Because an influenza pandemic would not damage physical infrastructure, the workplace would remain viable and day-to-day operations could continue based on the number of available personnel. Most organizations would not completely halt business operations because employees are ill. The organization may still need to produce products or provide services, interact with customers, and meet deadlines. A pandemic may result in an increase or decrease in demand for a business' products and/or services (e.g., effect of travel restrictions, restrictions on mass gatherings, need for hygiene supplies). Organizations should consider the potential impact of a pandemic on different product lines and/or production sites. Since essential functions are important at all times, it may be more appropriate to focus on day-to-day workload management during a pandemic. Consequently, organizations may need to rearrange priorities, rather than terminating daily operations or focusing only on essential functions as defined for a COOP situation.

Unlike other potential COOP situations that occur without warning, organizations can plan for a pandemic. Under normal conditions, if employees are on annual or sick leave, alternates are normally designated to provide back-up in the staff member's absence. To supplement the current workforce for conditions of significant absenteeism associated with a pandemic, organizations may consider cross-training and preparing ancillary workforce members (e.g., contractors, employees in other job titles/descriptions, retirees) to maintain daily functionality in the presence of anticipated staffing shortages.

#### *Essential vs. Non-critical/Non-essential Services*

Services provided by personnel may be categorized as critical or essential in light of their importance to business continuity (i.e., from the perspective of a business or organization) or in light of their contribution to maintaining critical infrastructure (i.e., from a societal or national perspective). Managers must make determinations about which employees perform essential functions at the business or organization level.

Organizations should carefully assess how a company functions, both internally and externally, to determine which staff, materials, procedures and equipment are absolutely necessary to keep the business operating by location and function during a pandemic. Operations critical to survival and recovery should be identified. Organizations should identify the suppliers, shippers, resources and other businesses they must interact with on a daily basis. Professional relationships with more than one supplier may be necessary should a primary contractor be unable to provide the required service. A disaster that shuts down a key supplier could be devastating to a business. In addition, organization-related domestic and international travel may be affected by a pandemic (e.g., quarantine, border closures). The analysis required for pandemic preparedness planning is not fundamentally different from that required for all-hazard COOP planning.

**Protecting Personnel during a Pandemic**

All organizations, whether government or private sector, large or small, are supported by three primary assets: people, communications, and physical infrastructure. Unlike other catastrophic events, an influenza pandemic will not directly affect the communications or physical infrastructure of an organization, but an influenza pandemic *will* directly affect an organization's people. Therefore, it is critical that organizations anticipate the potential impact of an influenza pandemic on personnel, and consequently, the organization's ability to continue essential functions. As part of that planning, organizations will need to ensure that reasonable measures are in place to protect the health of personnel during a pandemic.

*Characteristics of Influenza Transmission*

Understanding the characteristics of influenza transmission is important in order to assess the threat pandemic influenza poses to personnel in the workplace, as well as the efficacy and practicality of potential protective measures.

Human influenza virus is transmitted from person-to-person primarily via virus-laden large droplets (particles  $>5\ \mu\text{m}$  in diameter) that are generated when infected persons cough, sneeze, or speak. These large droplets can then be directly deposited onto the mucosal surfaces of the upper respiratory tract of susceptible persons who are near (i.e., typically within 3 feet of) the droplet source. Transmission also may occur through direct and indirect contact with infectious respiratory secretions.

Patients with influenza typically become infectious after a latent period of about 1 to 1.5 days and prior to becoming symptomatic. At about 2 days, most infected persons will develop symptoms of illness although some remain asymptomatic throughout their infection. This is important because even seemingly healthy asymptomatic individuals in early stages of influenza could be infectious to others.

*Vaccine and Antiviral Medications*

The primary strategies for preventing pandemic influenza are the same as those for seasonal influenza: (1) vaccination; (2) early detection and treatment with antiviral medications; and (3) the use of infection control measures to prevent transmission. However, when a pandemic begins, only a limited stockpile of partially matched pandemic vaccine may be available. A virus-specific vaccine to protect personnel will not be available until 4 to 6 months after isolation of the pandemic virus. Finally, the supply of antiviral drugs will be limited throughout a pandemic. Until sufficient stockpiles of antiviral drugs have been established, these medications may be available for treatment of only some symptomatic individuals. Therefore, the appropriate and thorough application of infection control measures remains the key to limiting transmission, delaying the spread of a pandemic, and protecting personnel.

*Infection Control Measures*

A pandemic may come in waves, each lasting weeks or months. Not all susceptible individuals will be infected in the first wave of a pandemic. Therefore preventing transmission by limiting exposure during the first wave may offer several advantages. First, by limiting exposure, people who are not infected during the first wave may have an increased chance of receiving virus-specific vaccine as it becomes available. Second, limiting exposure and delaying transmission can change the shape of the epidemic curve and mitigate the social and economic impact of a pandemic by reducing the number of people who become ill at any given time.

Within the workplace, the systematic application of infection control and social distancing measures during a pandemic should reduce employee-to-employee disease transmission rates, increase employee safety and confidence, and possibly reduce absenteeism.

Given the characteristics of influenza transmission, a few simple infection control measures may be effective in reducing the transmission of infection. Persons who are potentially infectious should: stay home if they are ill; cover their nose and mouth when coughing or sneezing, and use facial tissues to contain respiratory secretions and dispose of them in a waste container (respiratory hygiene/cough etiquette); and wash their hands (with soap and water, an alcohol-based hand rub, or antiseptic handwash) after having contact with respiratory secretions and contaminated objects/materials (hand hygiene). Persons who are around individuals with influenza-like symptoms should: maintain spatial separation of at least 3 feet from that individual; turn their head away from direct coughs or sneezes; and wash their hands (with soap and water, alcohol-based hand rub, or antiseptic handwash) after having contact with respiratory secretions and contaminated objects/materials.

Hand washing should be facilitated by making hand hygiene facilities and products readily available in schools and workplaces. Antibacterial handwashing products do not appear to offer an advantage over soap and water in most settings for removing influenza virus from hands, however health care facilities should continue to follow hand hygiene guidelines that recommend use of antimicrobial soaps and alcohol-based hand cleaners to protect against transmission of other microorganisms. For the duration of a pandemic, the deployment of infection control measures requires the ready availability of soap and water, hand sanitizer, tissues and waste receptacles, and environmental cleaning supplies.

Minimizing workplace exposure to pandemic influenza can be facilitated by: developing policies and strategies for isolating and excusing employees who become ill at work; allowing unscheduled and non-punitive leave for employees with ill household contacts; restricting business-related travel to affected geographic areas; and establishing guidelines for when employees who have become ill can return to work.

### *Social Distancing Measures*

Depending on the severity of a pandemic, and its anticipated effects on health care systems and the functioning of critical infrastructure, communities may recommend general measures to promote social distancing and the disaggregation of disease transmission networks. Within the workplace, social distancing measures could take the form of: guidelines modifying the frequency and type of face-to-face encounters that occur between employees (e.g., moratoriums on hand-shaking, substitution of teleconferences for face-to-face meetings, staggered breaks, posting of infection control guidelines in prominent locations); policies establishing flexible work hours or worksite, including telecommuting; and promotion of social distancing between employees and customers.

Some social distancing measures, such as the recommendation to maintain 3 feet of spatial separation between individuals or to otherwise limit face-to-face contact, may be adaptable to certain work environments and in appropriate settings should be sustainable indefinitely at comparatively minimal cost. Other community public health interventions (e.g., closure of schools and public transit systems, implementation of “snow day” restrictions) may increase rates of absenteeism and result in disruption of workflows and productivity. Low-cost or sustainable social distancing measures should be introduced within the workplace immediately after a community outbreak begins, and businesses should prepare for the possibility of measures that have the potential to disrupt their business continuity. Decisions as to how and when to implement community measures will be made on a case-by-case basis, with the Federal Government providing support and guidance to local officials.

*Use of Face Masks*

The benefit of wearing disposable surgical or procedure masks at school or in the workplace has not been established. Mask use by the public should be based on risk, including the frequency of exposure and closeness of contact with potentially infectious persons. Routine mask use in public should be permitted, but not required. The Federal Government will develop policies and guidance on the use and efficacy of masks. Other, more advanced respiratory protection may be indicated in certain instances, depending on the degree of exposure risk.

During a pandemic, persons who are diagnosed with influenza or who have a febrile respiratory illness should remain at home until the fever is resolved and the cough is resolving to avoid exposing others. If such symptomatic persons cannot stay home during the acute phase of their illness, consideration should be given to having them wear a surgical or procedure mask in public places when they may have close contact with other persons.

Although the use of surgical or procedure masks by asymptomatic individuals in community settings has not been demonstrated to be a public health measure to decrease infections during a community outbreak, persons may choose to wear a mask as part of individual protection strategies that include cough etiquette, hand hygiene, and avoiding public gatherings. If persons at risk for complications of influenza decide to wear masks during periods of increased respiratory illness activity in the community, it is likely they will need to wear them any time they are in a public place and when they are around other household members.

Any mask must be disposed of if it becomes moist. Individuals should wash their hands after touching or discarding a used mask. For more detailed information related to the use of face masks, the Department of Health and Human Services (HHS) has developed interim guidance on the use of masks to control influenza transmission, including the use of face masks and respirators in health care settings.

*Cleaning of Facilities and Equipment*

Given the concern regarding the spread of influenza through contaminated objects and surfaces, additional measures may be required to minimize the transmission of the virus through environmental surfaces such as sinks, handles, railings, and counters. Transmission from contaminated hard surfaces is unlikely, but influenza viruses may live up to 2 days on such surfaces. Surfaces that are frequently touched with hands should be cleaned at least daily during community outbreaks. At a minimum, organizations should develop procedures for cleaning facilities during an outbreak and develop procedures for employees to follow to keep work areas clean (e.g., disinfecting phones, keyboards, personal items). There is no evidence to support the efficacy of widespread disinfection of the environment or air.

HHS has developed recommendations regarding cleaning procedures as well as the handling of waste, eating utensils, and laundry for health care settings including home care. HHS will develop additional guidance regarding cleaning procedures and handling of potentially contaminated waste in non-health care settings such as the workplace.

*International Travel*

If an organization's employees or students travel outside the United States for business or educational reasons, plans should include consideration of the management of these personnel in the event of an



influenza pandemic.<sup>21</sup> Once a pandemic emerges, international travel may be disrupted. It is also possible that containment measures may be instituted affecting airline passenger movement. Organizations should anticipate that such measures might further aggravate staffing shortages.

### **Risk Management in Occupational Settings**

Organizations developing specific strategies to protect personnel should consider the factors that contribute to overall risk -- including the patterns of social contact entailed by specific positions, the health risk of employees for complications related to influenza, and other forms of social risk — and the feasibility of interventions designed to reduce social contacts or interrupt disease transmission. After completing such an assessment, organizations can tailor interventions to the particular needs of individuals, based on their personal health risk and the roles they play within the organization. To the extent possible, organizations should individualize the implementation of risk reduction strategies.

There are two basic categories of intervention: (1) *transmission interventions*, such as the use of facemasks and careful attention to cough etiquette and hand hygiene, which may reduce the likelihood that contacts with other people lead to disease transmission; and (2) *contact interventions*, such as substituting teleconferences for face-to-face meetings, telecommuting, the use of other social distancing techniques, and the implementation of liberal leave policies for persons with sick family members, which may eliminate or reduce the likelihood of contact with infected individuals. Interventions will have different costs and benefits, and be more or less appropriate or feasible, in different settings and for different individuals.

#### *Social Contacts in the Workplace*

The majority of Americans work in settings where social contacts occur. Some of these contacts, such as those between colleagues working on a joint project, may be regarded as voluntary or discretionary (i.e., face-to-face meetings are not absolutely necessary to maintain productivity), while others, such as those between sales clerks and customers, may be inherent to the nature of the position. Where feasible, voluntary or discretionary contacts may be reduced through contact interventions; where not, and in settings where social contacts are inherent to the nature of the position, risk reduction should be attempted through the implementation of transmission interventions. In theory, a contact intervention that reduces an individual's contacts by 30 percent is equivalent in terms of risk reduction to transmission interventions that reduce the probability of disease transmission by 30 percent.<sup>22</sup>

Some occupations can be classified as high risk because they will entail caring for persons with influenza (e.g., emergency medical services; police; fire and rescue; health care facility staff providers and support staff working in clinics, urgent care, and hospitals; and mortuary staff). The implementation of transmission interventions to protect personnel with such responsibilities is crucial, and organizations can additionally reduce risk by dedicating specific space and personnel for the care of patients with influenza and reducing or eliminating the connectivity of such areas and providers with the rest of the organization.

---

<sup>21</sup> All Federal Executive Branch employees abroad fall under Chief of Mission authority, regardless of their employment categories or location, except those under command of a U.S. area military commander or on the staff of an international organization. In coordination with the Department of State, each U.S. diplomatic mission abroad will prepare a mission-wide plan that will cover all mission personnel and their dependents. Individual agencies would not need to include their personnel serving abroad under Chief of Mission authority in their agency plans.

---

<sup>22</sup> In practice, the efficacy of contact interventions is easier to quantify than that of transmission interventions.



*Individual Risk for Complications Related to Influenza*

Risk group classifications will be modified as necessary in light of epidemiologic data collected during a pandemic. Individuals at high risk for severe and fatal infection cannot be predicted with certainty but are likely to include:

- Pregnant women;
- Persons with compromised immune systems due to cancer, AIDS, history of organ transplant, or other medical conditions;
- Persons less than age 65 with underlying chronic conditions;
- Persons age 65 or greater.

Organizations should consider providing additional protections for employees falling into categories identified as being at high risk for severe or fatal infection. Such protections could include reassignment from positions that entailed a high degree of unavoidable social contact or likely exposure to patients with influenza, and flexibility (where appropriate) in terms of worksite or work hours.

*Social Risk*

Some employees may be at increased personal risk during a pandemic because of limited access to health care services or other special needs not specified above. Risk reduction planning for such employees should be individualized.

**Roles and Responsibilities**

The responsibility for ensuring business continuity, COOP, and essential services, and providing for the health, safety, and security of employees, students, visitors, and customers is shared by the Federal, State, local, and tribal governments, private sector organizations, and academic institutions concerned. Federal, State, local, and tribal governments and the private sector have important and interdependent roles in preparing for, responding to, and recovering from a pandemic and ensuring that critical infrastructure is protected and sustained.

**The Federal Government**

The Federal Government will use all capabilities within its authority to support the private sector, State, local, and tribal entities, and schools and universities in preparedness and response activities. It will increase readiness to sustain critical infrastructure including essential Federal public health and medical functions during a pandemic and provide public health and medical support services under the *National Response Plan* (NRP). While HSPD-7 emphasizes protection of critical infrastructure from terrorism, it states that “all Federal departments and agencies shall work with the sectors relevant to their responsibilities to reduce the consequences of catastrophic failures not caused by terrorism.” HSPD-7 assigns responsibilities for CIP as noted below. Each Sector-Specific Agency is responsible for developing, implementing, and maintaining a sector-specific plan for conducting CIP activities within the sector, which include collaborating with all relevant Federal departments and agencies, State, local, and tribal governments, and the private sector.

Department of Homeland Security: DHS’s Office of National Security is the Government’s Executive Lead for COOP. The Office of National Security will develop guidance, planning procedures, and exercises for

an influenza pandemic and will monitor and report to the Executive Office of the President the readiness of departments and agencies to COOP during an influenza pandemic. DHS coordinates the overall national effort to enhance the protection of the critical infrastructure of the United States, and shall lead, integrate, and coordinate implementation of efforts among Federal departments and agencies, State, local, and tribal governments, and the private sector to protect critical infrastructure. DHS has overall coordination responsibilities for the 17 critical infrastructure sectors, and Sector-Specific Agencies, including DHS, have the lead for coordinating individual sectors. DHS coordinates protection activities for the following sectors: information technology; telecommunications; chemical; transportation systems (in collaboration with Department of Transportation), including mass transit, aviation, maritime, ground/surface, and rail and pipeline systems; emergency services; and postal and shipping. DHS coordinates with appropriate departments and agencies to ensure the protection of other key resources including dams, government facilities, and commercial facilities. DHS coordinates with the Nuclear Regulatory Commission (NRC) for the protection of nuclear power reactors, materials, and waste.

Department of Health and Human Services: HHS's primary responsibilities are those actions required to protect the health of all Americans and provide essential human services. Also, HHS in coordination with DHS will provide recommendations regarding measures Federal, State, local, and tribal agencies, private sector businesses, critical infrastructure entities, schools, and universities should employ to protect the health of personnel, customers, visitors, students, and teachers in order to aid in ensuring the continuity of essential services. HHS is the Sector-Specific Agency under HSPD-7 for public health, health care, and food (other than meat, poultry, and egg products).

Other Sector-Specific Agencies responsible under HSPD-7 for coordination with sector representatives are:

- Department of Agriculture for agriculture and food (meat, poultry, egg products);
- Environmental Protection Agency (EPA) for drinking water and water treatment systems;
- Department of Energy for energy, including the production refining, storage, and distribution of oil and gas, and electric power except for commercial nuclear power facilities (NRC);
- Department of the Treasury for banking and finance;
- Department of the Interior (DOI) for national monuments and icons; and
- Department of Defense (DOD) for the defense industrial base and defense critical infrastructure.

Other Important Federal Critical Infrastructure Responsibilities include:

- Department of State (DOS), in conjunction with DHS and other appropriate agencies, will work with foreign countries and international organizations to strengthen the protection of U.S. critical infrastructure.
- Department of Commerce (DOC), in coordination with DHS, will work with private sector, research, academic, and government organizations to promote critical infrastructure efforts, including using its authority under the Defense Production Act to ensure the timely availability of industrial products, materials, and services to meet homeland security requirements.

- Department of Education should coordinate with DHS and public and private education entities to collect and disseminate model pandemic influenza plans for adoption at the State, local, and tribal level, information on exercises and training, and monitor and share information on pandemic impacts.
- Department of Labor (DOL), in conjunction with HHS and other Sector-Specific Agencies, will work with the private sector to develop and disseminate information to promote the health and safety of personnel performing essential functions and roles.

### **State, Local, and Tribal Entities**

State, local, and tribal entities should have credible pandemic preparedness plans that address key response issues and outline strategies to mitigate the human, social, and economic consequences of a pandemic. State and local governments have received Federal Emergency Management Agency (FEMA) guidance for COOP planning (*Introduction to State and Local EOP Planning*), and should incorporate pandemic influenza specific planning. State, local, and tribal entities should work to improve communication between public health departments and private sector partners as well among various private and public entities including schools and universities. Elements of State, local, and tribal entities should be prepared to support national efforts to ensure that critical infrastructure is sustained. State, local, and tribal entities may serve as owners or operators for specific critical infrastructure sectors. In addition, State, local, and tribal entities may play a critical role for those critical infrastructure entities located within their communities. A preparedness checklist for State and local governments is available at [www.pandemicflu.gov](http://www.pandemicflu.gov).

### **The Private Sector**

Because private industry owns and operates the vast majority of the critical infrastructure in the United States, its involvement is crucial for successful implementation of CIP and the National Infrastructure Protection Plan. The private sector will play an integral role in a community response to pandemic influenza by protecting employees' and customers' health and safety, and mitigating impact to the economy and the functioning of society. Many businesses already have continuity of business operations plans that: (1) identify and ensure continued performance of essential functions, and (2) provide for continued supply of products and services at as close to normal levels as possible. Businesses should review and update these plans as appropriate given the pandemic threat and integrate and coordinate their planning with those on whom they depend for essential services and products, and with those entities that depend on them for essential services and products. Such business continuity planning should ensure that essential functions and vital services can be performed in the setting of significant absenteeism. Businesses and corporations should be prepared for public health interventions and recommendations that may increase absenteeism. Elements of the private sector should be prepared to support Federal, State, local, and tribal efforts to ensure that critical infrastructure is sustained. A preparedness checklist for organizations and businesses is provided in Appendix A and is available at [www.pandemicflu.gov](http://www.pandemicflu.gov).

### **Critical Infrastructure**

Protecting critical infrastructure is a shared responsibility requiring cooperation among all levels of government — Federal, State, local, and tribal — and the involvement of the private sector. Over 85 percent of critical infrastructure is owned and operated by the private sector. Sector-Specific Agencies should work in coordination with critical infrastructure sectors to develop guidance for individual organ-

ization plans for maintaining continuity of essential services as part of pandemic influenza planning and preparedness. Movement of essential personnel, goods and services, and maintenance of critical infrastructure are necessary during an influenza pandemic that could span months in any given community. The critical infrastructure entities must respond in a manner that allows them to maintain the essential elements of their operations for a prolonged period of time, in order to prevent severe disruption of life in our communities. Given the interdependence among critical infrastructure entities, coordination and cooperation among critical infrastructure entities and sectors with respect to identifying essential functions and engaging in critical intra- and inter-sector and cross-border planning will be essential.

### **Schools and Universities**

The roles and responsibilities of schools and universities in the area of continuity planning and protection of personnel are unique for several reasons. First, although there is no way to know the characteristics of a pandemic virus before it emerges, the planning assumptions suggest that in the absence of intervention influenza illness rates are likely to be highest among school-aged children (about 40 percent). Second, protecting and sustaining personnel in the workforce is of primary concern for effective continuity planning in public and private sector businesses and governmental entities. The focus in these sectors is on the workforce. In schools, the focus is primarily on protecting students. Third, universities must consider the potential impact of a pandemic on campus and dormitory closure, including the contingency plans for students who depend on student housing and campus food service. And fourth, schools and universities must also address continuity of instruction as part of continuity planning. Schools and universities (public and private) should review existing emergency response plans consistent with guidance provided by the Department of Education's Office of Safe and Drug-Free Schools, *Emergency Response and Crisis Management Guide*. Schools and universities should consider elements unique to pandemic influenza in their emergency response and crisis management plans to protect their faculty and students. Checklists for schools' and universities' actions for effective continuity planning are included in Appendix A and are available at [www.pandemicflu.gov](http://www.pandemicflu.gov).

### **Faith-Based Organizations and Community-Based Organizations**

Faith-based organizations (FBOs) and community-based organizations (CBOs) have a long tradition of helping Americans in need and together represent an integral part of our Nation's social service network. They help fill the needs of vulnerable populations and they help attend to the unmet needs that are not addressed by Federal disaster recovery programs. FBOs and CBOs have a long tradition of aiding victims of disasters. Communities should anticipate that in the event of multiple and widespread synchronous outbreaks during an influenza pandemic, the Federal Government may not possess sufficient resources or personnel to augment local capabilities. FBO/CBO and emergency management partnerships could be helpful in disaster mitigation, especially in a resource-constrained environment. FBOs and CBOs offer additional volunteer capacity; understanding of community needs and awareness of the most vulnerable populations; credibility with the community; access to social and population groups that may avoid interaction with government officials; and community influence. As locally based organizations with strong networks within communities, FBOs and CBOs are well situated to bring about grassroots involvement in mitigating the potential social and economic disruption associated with a pandemic. A preparedness checklist for FBOs and CBOs to ensure continuity of essential functions and protection of employees and volunteers is included in Appendix A and is available at [www.pandemicflu.gov](http://www.pandemicflu.gov).

## Individuals and Families

The critical role of individuals and families in controlling a pandemic cannot be overstated. The success or failure of infection control measures is ultimately dependent upon the acts of individuals -- practicing hand hygiene, cough etiquette, remaining home if ill or if a household member is ill, and complying with social distancing measures (see *Individual, Family, and Community Response to Pandemic Influenza* between Chapters 5 and 6). The collective response of all Americans will be crucial in mitigating the health, social, and economic impacts of a pandemic. A checklist of specific activities individuals and families can do now to prepare for a pandemic is included in Appendix A and is available at [www.pandemicflu.gov](http://www.pandemicflu.gov).

## Actions and Expectations

### 9.1. Pillar One: Preparedness and Communication

We must ensure preparedness, and the communication of roles and responsibilities for all levels of government and segments of societies including all Federal, State, local, and tribal governmental departments and agencies; private sector businesses and institutions; critical infrastructure entities; public and private schools and universities; and individuals and families.

#### *a. Planning for a Pandemic*

**9.1.1. Develop Federal implementation plans to include all components of the Federal Government and to address the full range of consequences of a pandemic, including human and animal health, security, transportation, economic, trade, and infrastructure considerations.**

- 9.1.1.1. DHS, in coordination with HHS, DOD, and DOL, shall provide pandemic influenza COOP guidance to the Federal departments and agencies within 6 months. Measure of performance: COOP planning and personnel protection guidance provided to all departments for use, as necessary, in updating departmental pandemic influenza response plans.
- 9.1.1.2. The Office of Personnel Management (OPM), in coordination with DHS, HHS, DOD, and DOL, shall provide guidance to the Federal departments and agencies on human capital management and COOP planning criteria related to pandemic influenza, within 3 months. Measure of performance: guidance provided to all departments for use, as necessary, in adjusting departmental COOP plans related to pandemic influenza.
- 9.1.1.3. OPM, in coordination with DHS, HHS, DOD, and DOL, shall update the guides *Telework: A Management Priority*, *A Guide for Managers, Supervisors, and Telework Coordinators*; *Telework 101 for Managers: Making Telework Work for You*; and, *Telework 101 for Employees: Making Telework Work for You*, to provide guidance to Federal departments regarding workplace options during a pandemic, within 3 months. Measure of performance: updated telework guidance provided to all departments for use, as necessary, in updating departmental COOP plans related to pandemic influenza.

**9.1.2. Continue to work with States, localities, and tribal entities to integrate non-health sectors, including the private sector and critical infrastructure entities, in these planning efforts.**

- 9.1.2.1. DHS, in coordination with Sector-Specific Agencies, critical infrastructure owners and operators, and States, localities and tribal entities, shall develop sector-specific planning guidelines focused on sector-specific requirements and cross-sector dependencies, within 6 months. Measure of performance: planning guidelines developed for each sector.
- 9.1.2.2. DHS, in coordination with States, localities and tribal entities, shall support private sector preparedness with education, exercise, training, and information sharing outreach programs, within 6 months. Measure of performance: preparedness exercises established with private sector partners in all States and U.S. territories.

***b. Communicating Expectations and Responsibilities*****9.1.3. Provide guidance to the private sector and critical infrastructure entities on their role in the pandemic response, and considerations necessary to maintain essential services and operations despite significant and sustained worker absenteeism.**

- 9.1.3.1. DHS, in coordination with all the Sector-Specific Agencies, shall conduct forums, conferences, and exercises with key critical infrastructure private sector entities and international partners to identify essential functions and critical planning, response and mitigation needs within and across sectors, and validate planning guidelines, within 6 months. Measure of performance: planning guidelines validated by collaborative exercises that test essential functions and critical planning, response, and mitigation needs.
- 9.1.3.2. DHS, in coordination with all the Sector-Specific Agencies, shall develop and coordinate guidance regarding business continuity planning and preparedness with the owners/operators of critical infrastructure and develop a Critical Infrastructure Influenza Pandemic Preparedness, Response, and Recovery Guide tailored to national goals and capabilities and to the specific needs identified by the private sector, within 6 months. Measure of performance: Critical Infrastructure Influenza Pandemic Preparedness, Response, and Recovery Guide developed and published on [www.pandemicflu.gov](http://www.pandemicflu.gov).

**9.1.4. Provide guidance to individuals on infection control behaviors they should adopt pre-pandemic, and the specific actions they will need to take during a severe influenza season or pandemic, such as self-isolation and protection of others if they themselves contract influenza.**

- 9.1.4.1. 9.1.4.1. HHS, in coordination with DHS, DOL, OPM, Department of Education, VA, and DOD, shall develop sector-specific infection control guidance to protect personnel, governmental and public entities, private sector businesses, and CBOs and FBOs, within 6 months. Measure of performance: sector-specific guidance and checklists developed and disseminated on [www.pandemicflu.gov](http://www.pandemicflu.gov).



- 9.1.4.2. HHS, in coordination with DHS, DOL, EPA, Department of Education, VA, and DOD, shall develop interim guidance regarding environmental management and cleaning practices including the handling of potentially contaminated waste material, within 3 months, and revise as additional data becomes available. Measure of performance: development and publication of guidance and check-lists on [www.pandemicflu.gov](http://www.pandemicflu.gov) and dissemination through other channels.

### **9.3. Pillar Three: Response and Containment**

We recognize that a virus with pandemic potential anywhere represents a risk to populations everywhere. Once health authorities signal that sustained and efficient human-to-human spread of the virus has occurred, a cascade of response mechanisms will be initiated, from the site of the documented transmission to locations around the globe. This response must ensure that critical infrastructure, essential services, and the economy are sustained.

#### ***a. Sustaining Infrastructure, Essential Services, and the Economy***

##### **9.3.1. Encourage the development of coordination mechanisms across American industries to support the above activities during a pandemic.**

- 9.3.1.1. DHS shall map and model critical infrastructure interdependencies across and within sectors to share critical information with sectors and identify national challenges during a pandemic, within 6 months. Measure of performance: critical infrastructure modeling capability established and mapping of critical infrastructure interdependencies completed.
- 9.3.1.2. DHS shall develop and operate a national-level monitoring and information-sharing system for core essential services to provide status updates to critical infrastructure dependent on these essential services, and aid in sharing real-time impact information, monitoring actions, and prioritizing national support efforts for preparedness, response, and recovery of critical infrastructure sectors within 12 months. Measure of performance: national-level critical infrastructure monitoring and information-sharing system established and operational.

##### **9.3.2. Provide guidance to activate contingency plans to ensure that personnel are protected, that the delivery of essential goods and services is maintained, and that sectors remain functional despite significant and sustained worker absenteeism.**

- 9.3.2.1. DHS shall coordinate Federal, State, local, and tribal actions/options/capability requirements (legislative and regulatory additions/changes and waivers, personnel and material resources, and financial) to develop and implement tailored support packages to address critical infrastructure systems and essential operational requirements at each phase of the pandemic: planning, preparedness, response, mitigation, and recovery. Measure of performance: support packages ensure essential functions of all critical infrastructure sectors sustained during a pandemic.



## APPENDIX A

### Guidance for Federal Department Planning

Federal departments and agencies are expected to develop their own pandemic plans. This guidance is intended to facilitate department and agency planning.

### Relationship between the *Strategy*, the Implementation Plan, and Department Plans

**The *National Strategy for Pandemic Influenza (Strategy)*:** The *Strategy* articulates the high-level principles and approach of the Federal Government to the threat of an influenza pandemic.

**Implementation Plan for the National Strategy (Plan):** This Plan proposes actions across the Federal Government in support of the Strategy, and describes expectations of non-Federal entities, including State, local, and tribal governments, the private sector, international partners, and individuals. While the Strategy is built upon pillars (preparedness, surveillance, response), this Plan segregates action on a functional basis (international efforts, transportation and borders, human health, animal health). It also addresses crosscutting issues such as economic issues and the relevant legal authorities in each of these functional areas. Finally, it provides a “playbook” and algorithm that the Federal Government will follow in its response to a pandemic.

**Department Plans:** Department plans should be operational documents. They should first articulate the manner in which the Department will discharge its responsibilities as defined in this Plan. In addition to describing the manner in which the Department will support the Federal Government efforts, plans should address the operational approach to employee safety, continuity of operations, and the manner in which the Department will communicate to its stakeholders as described below.

### Guidance for Department Planning

Unlike other catastrophic events, a pandemic will not be geographically or temporally bounded, and will not directly affect the physical infrastructure of an organization. These facts lead to unique planning considerations. Institutional planning efforts should build upon existing continuity of operations planning by the organization, but be expanded to address the following questions:

1. How will the Department protect the health and safety of its employees?
2. What are the Department’s essential functions and services, and how will these be maintained in the event of significant and sustained absenteeism?
3. How will the Department support the Federal response to a pandemic, and States, localities, and tribal entities?
4. How and what will the Department communicate to its stakeholders during a pandemic?

*Appendix A**Protecting the Health of Employees*

This portion of the plan should build upon existing employee health and safety efforts. HHS, in coordination with the Department of Labor, and other departments and agencies, will provide recommendations on the protection of employee health to inform this planning.

*Maintaining Essential Functions and Services*

Maintaining essential functions and services relates to continuity of operations. While some of the guidance in Federal Preparedness Circular - 65, Federal Executive Branch Continuity of Operations (FPC-65) may not seem to be directly relevant to pandemic planning, most of the principles are relevant to the continuity considerations raised by a pandemic.

*Supporting the Federal Response and States, Localities and Tribal Entities*

This Plan provides high-level direction to departments and agencies for the actions that they are to take in support of the Strategy. Department plans should articulate the manner in which these actions will be executed by the Department, including the roles and responsibilities of operating divisions and more detailed descriptions of the ways the Department will support the Federal, State, local, and tribal response.

*Communicating to Stakeholders*

Every department and agency has connections to a unique group of stakeholders, whether private sector entities, non-governmental organizations (NGOs), or individuals. As the “face of the Federal Government” for these stakeholders, departments should identify the messages that it will communicate during a pandemic.

## **Guidance for Organizations and Businesses**

Federal departments and agencies; State, local, and tribal governments and organizations; and public and private businesses must ensure preparedness and the communication of roles and responsibilities related to continuity planning and protection of personnel. In the event of pandemic influenza, organizations and businesses will play a key role in protecting employees’ health and safety as well as limiting the negative impact to the economy and society. Planning for pandemic influenza is critical. The Department of Health and Human Services (HHS) has developed the following checklist for large organizations and businesses. It identifies important, specific activities organizations and businesses can do now to prepare. Further information can be found at [www.pandemicflu.gov](http://www.pandemicflu.gov). This checklist is applicable to all organizations and businesses, public or private.

### **1. Plan for the impact of a pandemic on your business or organization**

- 1.1. Identify a pandemic coordinator and/or team with defined roles and responsibilities for preparedness and response planning. The planning process should include input from labor representatives.
- 1.2. Identify essential employees and other critical inputs (e.g., raw materials, suppliers, sub-contractor services/products, logistics) required to maintain business operations by location and function during a pandemic.
- 1.3. Train and prepare ancillary workforce (e.g., contractors, employees in other job titles/descriptions, retirees).

- 
- 1.4. Develop and plan for scenarios likely to result in an increase or decrease in demand for your products and/or services during a pandemic (e.g., effect of restrictions on mass gatherings, need for hygiene supplies).
  - 1.5. Determine potential impact of a pandemic on organization or business financials using multiple possible scenarios that affect different product lines and/or production sites.
  - 1.6. Determine potential impact of a pandemic on organization-related domestic and international travel (e.g., quarantine, border closures).
  - 1.7. Find up-to-date reliable pandemic information from community public health, emergency management, and other sources and make sustainable links.
  - 1.8. Establish an emergency communications plan and revise periodically. This plan includes identification of key contacts (with back-ups), chain of communications (including suppliers and customers), and processes for tracking and communicating business and employee status.
  - 1.9. Implement an exercise/drill to test your plan and revise periodically.
- 2. Plan for the impact of a pandemic on your employees and customers**
- 2.1. Forecast and allow for employee absence during a pandemic due to factors such as personal illness, family member illness, community containment measures and quarantines, school and/or business closures, and public transportation closures.
  - 2.2. Implement guidelines to modify frequency and type of face-to-face contact (e.g., hand-shaking, seating in meetings, office layout, shared workstation) among employees and between employees and customers.
  - 2.3. Encourage and track annual influenza vaccination for employees during regular influenza seasons.
  - 2.4. Evaluate employee access and availability to health care services during a pandemic, and improve services as needed.
  - 2.5. Evaluate and improve access to and availability to mental health and social services during a pandemic, including corporate, community, and faith-based resources, and improve services as needed.
  - 2.6. Identify employees and key customers with special needs, and incorporate the requirements of such person into your preparedness plan.
- 3. Establish policies to be implemented during a pandemic**
- 3.1. Establish policies for employee compensation and sick leave absences unique to a pandemic (e.g., non-punitive, liberal leave), including policies on when a previously ill person is no longer infectious and can return to work after illness.
  - 3.2. Establish policies for flexible worksite (e.g., telecommuting) and flexible work hours (e.g., staggering shifts).
-

- 3.3. Establish policies for preventing influenza spread at the worksite (e.g., promoting respiratory hygiene/cough etiquette, increasing social distancing among employees and between employees and customers, and prompt exclusion of people with influenza symptoms).
- 3.4. Establish policies for personnel who have been exposed to pandemic influenza, are suspected to be ill, or become ill at the worksite (e.g., infection control response, immediate mandatory sick leave).
- 3.5. Establish policies for restricting travel to affected geographic areas (consider both domestic and international sites) and for evacuating employees working in or near an affected area when an outbreak begins, and establish guidance for employees returning from affected areas.
- 3.6. Set up authorities, triggers, and procedures for activating and terminating the organization's response plan, altering business operations (e.g., shutting down operations in affected areas), and transferring business knowledge to key employees.
- 4. Allocate resources to protect your employees and customers during a pandemic**
  - 4.1. Provide sufficient and available infection control supplies. The deployment of infection control measures requires the ready availability of soap and water, hand sanitizer, tissues and waste receptacles, environmental cleaning supplies, for the duration of a pandemic.
  - 4.2. Enhance communications and information technology infrastructure as needed to support employee telecommuting and remote customer access.
  - 4.3. Ensure availability of medical consultation and advice for emergency response.
- 5. Communicate to and educate your employees**
  - 5.1. Develop and disseminate programs and materials covering pandemic fundamentals (e.g., signs and symptoms of influenza, modes of transmission), personal and family protection, and response strategies (e.g., hand hygiene, cough/sneeze etiquette, contingency plans).
  - 5.2. Anticipate employee fear and anxiety, rumors, and misinformation and plan communications accordingly.
  - 5.3. Ensure communications are culturally and linguistically appropriate.
  - 5.4. Disseminate information to employees about the organizational pandemic preparedness plan.
  - 5.5. Provide information for the at-home care of ill employees and family members.
  - 5.6. Develop platforms (e.g., hotlines, dedicated websites) for communicating pandemic status and actions to employees, vendors, suppliers, and customers inside and outside the worksite in a consistent and timely way, including redundancies in the emergency contact system.
  - 5.7. Identify community sources for timely and accurate pandemic information (domestic and international) and resources for obtaining countermeasures (e.g., vaccines and antiviral medications).

## 6. Coordinate with external organizations and help your community

- 6.1. Collaborate with insurers, health plans, and major health care facilities to share your pandemic plans and understand their capabilities and plans.
- 6.2. Collaborate with Federal, State, and local public health agencies and/or emergency responders to participate in their planning processes, share your pandemic plans, and understand their capabilities and plans.
- 6.3. Communicate with local and/or State public health agencies and/or emergency responders about the assets and/or services your business could contribute to the community.
- 6.4. Share best practices with other businesses in your community, chambers of commerce, and associations to improve community response efforts.

## Guidance for Schools (K-12)

Schools (K-12) must ensure preparedness, and the communication of roles and responsibilities related to ensuring continuity of instruction and protection of students and personnel. Local educational agencies (LEAs) play an integral role in protecting the health and safety of their district's staff, students, and their families. HHS, in coordination with the Department of Education, has developed the following checklist to assist LEAs in developing and/or improving plans to prepare for and respond to an influenza pandemic.

Building a strong relationship with the local health department is critical for developing a meaningful plan. The key planning activities in this checklist build upon existing contingency plans recommended for school districts by the Department of Education (*Practical Information on Crisis Planning: A Guide For Schools and Communities*). Further information can be found at [www.pandemicflu.gov](http://www.pandemicflu.gov).

### 1. Planning and Coordination

- 1.1. Identify the authority responsible for declaring a public health emergency at the State and local levels and for officially activating the district's pandemic influenza response plan.
- 1.2. Identify for all stakeholders the legal authorities responsible for executing the community operational plan, especially those authorities responsible for case identification, isolation, quarantine, movement restriction, health care services, emergency care, and mutual aid.
- 1.3. As part of the district's crisis management plan, address pandemic influenza preparedness, involving all relevant stakeholders in the district (e.g., lead emergency response agency, district administrators, local public health representatives, school health and mental health professionals, teachers, food services directors, and parent representatives). This committee is accountable for articulating strategic priorities and overseeing the development and execution of the district's operational pandemic plan.
- 1.4. Work with local and/or State health departments and other community partners to establish organizational structures such as the Incident Command System (ICS), to manage the execution of the district's pandemic influenza plan. An ICS is a standardized organization

structure that establishes a line of authority and common terminology and procedures to be followed in response to an incident. Ensure compatibility between the district's established ICS and the local/State health department's and State education department's ICS.

- 1.5. Delineate accountability and responsibility as well as resources for key stakeholders engaged in planning and executing specific components of the operational plan. Ensure that the plan includes timelines, deliverables, and performance measures.
- 1.6. Work with your local and/or State health department and State education agencies to coordinate with their pandemic plans. Ensure that pandemic planning is coordinated with the community's pandemic plan as well as the State department of education's plan.
- 1.7. Test the linkages between the district's ICS and the local/State health department's and State education department's ICS.
- 1.8. Contribute to the local health department's operational plan for surge capacity of health care and other services to meet the needs of the community (e.g., schools designated as contingency hospitals, schools feeding vulnerable populations, community utilizing LEA's health care and mental health staff). In an affected community, at least two pandemic disease waves (about 6-8 weeks each) are likely over several months.
- 1.9. Incorporate into the pandemic influenza plan the requirements of students with special needs (e.g., low income students who rely on the school food service for daily meals), those in special facilities (e.g., juvenile justice facilities), as well as those who do not speak English as their first language.
- 1.10. Participate in exercises of the community's pandemic plan.
- 1.11. Work with the local health department to address provision of psychosocial support services for the staff, students, and their families during and after a pandemic.
- 1.12. Consider developing in concert with the public health department a surveillance system that would alert the public health department to a substantial increase in absenteeism among students.
- 1.13. Implement an exercise/drill to test your pandemic plan and revise it periodically.
- 1.14. Share what you have learned from developing your preparedness and response plan with other LEAs as well as private schools within the community to improve community response efforts.

## **2. Continuity of Student Learning and Core Operations**

- 2.1. Develop scenarios describing the potential impact of a pandemic on student learning (e.g., student and staff absences), school closings, and extracurricular activities based on having various levels of illness among students and staff.
- 2.2. Develop alternative procedures to ensure continuity of instruction (e.g., web-based distance instruction, telephone trees, mailed lessons and assignments, instruction via local radio or television stations) in the event of district school closures.

- 2.3. Develop a continuity of operations plan for essential central office functions (including payroll, ongoing communication with students and parents).

### **3. Infection Control Policies and Procedures**

- 3.1. Work with local health department to implement effective infection prevention policies and procedures that help limit the spread of influenza at schools in the district (e.g., promotion of hand hygiene, cough/sneeze etiquette). Make good hygiene a habit now in order to help protect children from many infectious diseases such as influenza.
- 3.2. Provide sufficient and accessible infection prevention supplies (e.g., soap, alcohol-based/waterless hand hygiene products, tissues and receptacles for their disposal).
- 3.3. Establish policies and procedures for students and staff sick leave absences unique to a pandemic influenza (e.g., non-punitive, liberal leave).
- 3.4. Establish sick leave policies for staff and students suspected to be ill or who become ill at school. Staff and students with known or suspected pandemic influenza should not remain at school and should return only after their symptoms resolve and they are physically ready to return to school.
- 3.5. Establish policies for transporting ill students.
- 3.6. Ensure that the LEA pandemic plan for school-based health facilities conform to those recommended for health care settings.

### **4. Communications Planning**

- 4.1. Assess readiness to meet communications needs in preparation for an influenza pandemic, including regular review, testing, and updating of communications plans.
- 4.2. Develop a dissemination plan for communication with staff, students, and families, including lead spokespersons and links to other communication networks.
- 4.3. Ensure language, culture, and reading level appropriateness in communications by including community leaders representing different language and/or ethnic groups on the planning committee, asking for their participation in both document planning and the dissemination of public health messages within their communities.
- 4.4. Develop and test platforms (e.g., hotlines, telephone trees, dedicated websites, local radio or TV stations) for communicating pandemic status and actions to school district staff, students, and families.
- 4.5. Develop and maintain up-to-date communications contacts of key public health and education stakeholders and use the network to provide regular updates as the influenza pandemic unfolds.
- 4.6. Ensure the provision of redundant communication systems/channels that allow for the expedited transmission and receipt of information.



- 4.7. Advise district staff, students, and families where to find up-to-date and reliable pandemic information from Federal, State, and local public health sources.
- 4.8. Disseminate information about the LEA's pandemic influenza preparedness and response plan (e.g., continuity of instruction, community containment measures).
- 4.9. Disseminate information from public health sources covering routine infection control (e.g., hand hygiene, cough/sneeze etiquette), pandemic influenza fundamentals (e.g., signs and symptoms of influenza, modes of transmission), as well as personal and family protection and response strategies (e.g., guidance for the at-home care of ill students and family members).
- 4.10. Anticipate the potential fear and anxiety of staff, students, and families as a result of rumors and misinformation and plan communications accordingly.

## Guidance for Colleges and Universities

Colleges and universities must ensure preparedness, and the communication of roles and responsibilities related to ensuring continuity of instruction and protection of students and personnel. In the event of an influenza pandemic, colleges and universities will play an integral role in protecting the health and safety of students, employees and their families. HHS, in coordination with the Department of Education, has developed the following checklist as a framework to assist colleges and universities to develop and/or improve plans to prepare for and respond to an influenza pandemic. Further information can be found at [www.pandemicflu.gov](http://www.pandemicflu.gov).

### 1. Planning and Coordination

- 1.1. Identify a pandemic coordinator and response team (including campus health services and mental health staff, student housing personnel, security, communications staff, physical plant staff, food services director, academic staff, and student representatives) with defined roles and responsibilities for preparedness, response, and recovery planning.
- 1.2. Delineate accountability and responsibility as well as resources for key stakeholders engaged in planning and executing specific components of the operational plan. Ensure that the plan includes timelines, deliverables, and performance measures.
- 1.3. Incorporate into the pandemic plan scenarios that address college/university functioning based upon having various levels of illness in students and employees and different types of community containment interventions. Plan for different outbreak scenarios including variations in severity of illness, mode of transmission, and rates of infection in the community. Issues to consider include:
  - cancellation of classes, sporting events, and/or public events;
  - closure of campus, student housing, and/or public transportation;
  - assessment of the suitability of student housing for quarantine of exposed and/or ill students;
  - contingency plans for students who depend on student housing and food services (e.g., international students or students who live too far away to travel home);

- contingency plans for maintaining research laboratories, particularly those using animals; and
  - stockpiling non-perishable food and equipment that may be needed in the case of an influenza pandemic.
- 1.4. Work with local public health authorities to identify legal authority, decision makers, trigger points, and thresholds to institute community containment measures such as closing (and re-opening) the college/university. Identify and review the college/university's legal responsibilities and authorities for executing infection control measures, including case identification, reporting information about ill students and employees, isolation, movement restriction, and provision of health care on campus.
  - 1.5. Ensure that pandemic influenza planning is consistent with any existing college/university emergency operations plan, and is coordinated with the pandemic plan of the community and of the State higher education agency.
  - 1.6. Work with the local health department to discuss an operational plan for surge capacity for health care and other mental health and social services to meet the needs of the college/university and community during and after a pandemic.
  - 1.7. Establish an emergency communication plan and revise regularly. This plan should identify key contacts with local and State public health officials as well as the State's higher education officials (including back-ups) and the chain of communications, including alternate mechanisms.
  - 1.8. Test the linkages between the college/university's ICS and the ICS of the local and/or State health department and the State's higher education agency.
  - 1.9. Implement an exercise/drill to test your plan, and revise it regularly.
  - 1.10. Participate in exercises of the community's pandemic plan.
  - 1.11. Share what you have learned from developing your preparedness and response plan with other colleges/universities to improve community response efforts.
- 2. Continuity of Student Learning and Operations**
    - 2.1. Develop and disseminate alternative procedures to ensure continuity of instruction (e.g., web-based distance instruction, telephone trees, mailed lessons and assignments, instruction via local radio or television stations) in the event of college/university closures.
    - 2.2. Develop a continuity of operations plan for maintaining the essential operations of the college/university including payroll; ongoing communication with employees, students and families; security; maintenance; as well as housekeeping and food service for student housing.
- 3. Infection Control Policies and Procedures**
    - 3.1. Implement infection control policies and procedures that help limit the spread of influenza on campus (e.g., promotion of hand hygiene, cough/sneeze etiquette). Make good hygiene a

habit now in order to help protect employees and students from many infectious diseases such as influenza. Encourage students and staff to get annual influenza vaccine.

- 3.2. Procure, store, and provide sufficient and accessible infection prevention supplies (e.g., soap, alcohol-based hand hygiene products, tissues and receptacles for their disposal).
- 3.3. Establish policies for employee and student sick-leave absences unique to pandemic influenza (e.g., non-punitive, liberal leave).
- 3.4. Establish sick leave policies for employees and students suspected to be ill or who become ill on campus. Employees and students with known or suspected pandemic influenza should not remain on campus and should return only after their symptoms resolve and they are physically ready to return to campus.
- 3.5. Establish a pandemic plan for campus-based health care facilities that addresses issues unique to health care settings. Ensure health services and clinics have identified critical supplies needed to support a surge in demand and take steps to have those supplies on hand.
- 3.6. Adopt CDC travel recommendations during an influenza pandemic, and be able to support voluntary and mandatory movement restrictions. Recommendations may include restricting travel to and from affected domestic and international areas, recalling non-essential employees working in or near an affected area when an outbreak begins, and distributing health information to persons who are returning from affected areas.

#### **4. Communications Planning**

- 4.1. Assess readiness to meet communications needs in preparation for an influenza pandemic, including regular review, testing, and updating of communications plans that link with public health authorities and other key stakeholders.
- 4.2. Develop a dissemination plan or communication with employees, students, and families, including lead spokespersons and links to other communication networks. Ensure language, culture, and reading level appropriateness in communications.
- 4.3. Develop and test platforms (e.g., hotlines, telephone trees, dedicated websites, local radio or television) for communicating college/university response and actions to employees, students, and families.
- 4.4. Ensure the provision of redundant communication systems/channels that allow for the expedited transmission and receipt of information.
- 4.5. Advise employees and students where to find up-to-date and reliable pandemic information from Federal, State, and local public health sources.
- 4.6. Disseminate information about the college/university's pandemic preparedness and response plan. This should include the potential impact of a pandemic on student housing closure, and the contingency plans for students who depend on student housing and campus food service, including how student safety will be maintained for those who remain in student housing.

- 4.7. Disseminate information from public health sources covering routine infection control (e.g., hand hygiene, cough/sneeze etiquette), pandemic influenza fundamentals (e.g., signs and symptoms of influenza, modes of transmission), personal and family protection and response strategies, and the at-home care of ill students or employees and their family members.
- 4.8. Anticipate and plan communications to address the potential fear and anxiety of employees, students, and families that may result from rumors or misinformation.

## Guidance for Faith-Based and Community-Based Organizations

The collaboration of faith-based organizations (FBOs) and community-based organizations (CBOs) with public health agencies will be essential in providing the public's health and safety if and when an influenza pandemic occurs. HHS has developed the following checklist for FBOs and CBOs. This checklist identifies important, specific activities FBOs and CBOs can do now to prepare. Further information can be found at [www.pandemicflu.gov](http://www.pandemicflu.gov).

### 1. Plan for the impact of a pandemic on your organization and its mission

- 1.1. Assign key staff with the authority to develop, maintain, and act upon an influenza pandemic preparedness and response plan.
- 1.2. Determine the potential impact of a pandemic on your organization's usual activities and services. Plan for situations likely to require increasing, decreasing, or altering the services your organization delivers.
- 1.3. Determine the potential impact of a pandemic on outside resources that your organization depends on to deliver its services (e.g., supplies, travel).
- 1.4. Outline what the organizational structure will be during an emergency and revise periodically. The outline should identify key contacts with multiple back-ups, roles and responsibilities, and who is supposed to report to whom.
- 1.5. Identify and train essential staff (including full-time, part-time, and unpaid or volunteer staff) needed to carry on your organization's work during a pandemic. Include back up plans, cross-train staff in other jobs so that if staff are sick, others are ready to come in to carry on the work.
- 1.6. Test your response and preparedness plan using an exercise or drill, and review and revise your plan as needed.

### 2. Communicate with and educate your staff, members, and persons in the community that you serve

- 2.1. Find up-to-date, reliable pandemic information and other public health advisories from State and local health departments, emergency management agencies, and HHS. Make this information available to your organization and others.
- 2.2. Distribute materials with basic information about pandemic influenza: signs and symptoms, how it is spread, ways to protect yourself and your family (e.g., respiratory hygiene and

cough etiquette), family preparedness plans, and how to care for ill persons at home.

- 2.3. When appropriate, include basic information about pandemic influenza in public meetings (e.g., sermons, classes, trainings, small group meetings, announcements).
  - 2.4. Share information about your pandemic preparedness and response plan with staff, members, and persons in the communities that you serve.
  - 2.5. Develop tools to communicate to staff, members, and persons in the communities that you serve information about pandemic status and your organization's actions. This might include websites, flyers, local newspaper announcements, pre-recorded widely distributed phone messages, etc.
  - 2.6. Consider your organization's unique contribution to addressing rumors, misinformation, fear, and anxiety.
  - 2.7. Advise staff, members, and persons in the communities you serve to follow information provided by public health authorities -- State and local health departments, emergency management agencies, and HHS.
  - 2.8. Ensure that what you communicate is appropriate for the cultures, languages, and reading levels of your staff, members, and persons in the communities that you serve.
- 3. Plan for the impact of a pandemic on your staff, members, and the communities that you serve**
- 3.1. Plan for staff absences during a pandemic due to personal and/or family illnesses, quarantines, and school, business, and public transportation closures. Staff may include full-time, part-time, and volunteer personnel.
  - 3.2. Work with local health authorities to encourage yearly influenza vaccination for staff, members, and persons in the communities that you serve.
  - 3.3. Evaluate access to mental health and social services during a pandemic for your staff, members, and persons in the communities that you serve; improve access to these services as needed.
  - 3.4. Identify persons with special needs (e.g., elderly, disabled, limited English speakers) and be sure to include their needs in your response and preparedness plan. Establish relationships with them in advance so they will expect and trust your presence during a crisis.
- 4. Set up policies to follow during a pandemic**
- 4.1. Set up policies for non-penalized leave for personal illness or care for sick family members during a pandemic.
  - 4.2. Set up mandatory sick-leave policies for staff suspected to be ill, or who become ill at the worksite. Employees should remain at home until their symptoms resolve and they are physically ready to return to duty.
  - 4.3. Set up policies for flexible work hours and working from home.

- 4.4. Evaluate your organization's usual activities and services (including rites and religious practices if applicable) to identify those that may facilitate virus spread from person to person. Set up policies to modify these activities to prevent the spread of pandemic influenza (e.g., guidance for respiratory hygiene and cough etiquette, and instructions for persons with influenza symptoms to stay home and phone the organization rather than visit in person).
- 4.5. Follow HHS travel recommendations during an influenza pandemic. Recommendations may include restricting travel to affected domestic and international sites, recalling non-essential staff working in or near an affected site when an outbreak begins, and distributing health information to persons who are returning from affected areas.
- 4.6. Set procedures for activating your organization's response plan when an influenza pandemic is declared by public health authorities and altering your organization's operations accordingly.
5. **Allocate resources to protect your staff, members, and persons in the communities that you serve during a pandemic**
  - 5.1. Determine the amount of supplies needed to promote respiratory hygiene and cough etiquette and how they will be obtained.
  - 5.2. Consider focusing your organization's efforts during a pandemic to providing services that are most needed during the emergency (e.g., mental/spiritual health or social services).
6. **Coordinate with external organizations and help your community**
  - 6.1. Understand the roles of Federal, State, and local public health agencies and emergency responders and what to expect and what not to expect from each in the event of a pandemic.
  - 6.2. Work with local and/or State public health agencies, emergency responders, local health care facilities, and insurers to understand their plans and what they can provide, share about your preparedness and response plan and what your organization is able to contribute, and take part in their planning. Assign a point of contact to maximize communication between your organization and your State and local public health systems.
  - 6.3. Coordinate with emergency responders and local health care facilities to improve availability of medical advice and timely/urgent health care services for your staff, members, and persons in the communities that you serve.
  - 6.4. Share what you've learned from developing your preparedness and response plan with other FBOs and CBOs to improve community response efforts.
  - 6.5. Work together with other FBOs and CBOs in your local area and through networks (e.g., denominations, associations) to help your communities prepare for pandemic influenza.

## Planning Guidance for Individuals and Families

Individuals and families can prepare for an influenza pandemic now. This guidance is designed to help you understand the threat of a pandemic influenza outbreak in our country and your community.

*Appendix A*

It describes common sense actions that you can take in preparing for a pandemic. Each individual and family should know both the magnitude of what can happen during a pandemic outbreak and what actions you can take to help lessen the impact of an influenza pandemic on you and your community. Further information including a planning checklist can be found at [www.pandemicflu.gov](http://www.pandemicflu.gov).

### **Pandemic Influenza: What Individuals Need to Know**

An influenza (flu) pandemic is a widespread outbreak of disease that occurs when a new influenza virus appears that people have not been exposed to before. Pandemics are different from seasonal outbreaks of influenza. Seasonal influenza outbreaks are caused by viruses that people have already been exposed to; influenza shots are available to help prevent widespread illness, and impacts on society are less severe. Pandemic influenza spreads easily from person to person and can cause serious illness because people do not have immunity to the new virus.

#### *Some Differences between Seasonal Flu and Pandemic Flu*

| <b>Seasonal Flu</b>                                                                                                                                                                          | <b>Pandemic Flu</b>                                                                                                                                                                                                                                                                                                               |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Caused by influenza viruses that are similar to those already affecting people.                                                                                                              | Caused by a new influenza virus that people have not been exposed to before. Likely to be more severe, affect more people, and cause more deaths than seasonal influenza because people will not have immunity to the new virus.                                                                                                  |
| Symptoms include fever, cough, runny nose, and muscle pain. Deaths can be caused by complications such as pneumonia.                                                                         | Symptoms similar to the common flu may be more severe and complications more serious.                                                                                                                                                                                                                                             |
| Healthy adults usually not at risk for serious complications (the very young, the elderly, and those with certain underlying health conditions at increased risk for serious complications). | Healthy adults may be at increased risk for serious complications.                                                                                                                                                                                                                                                                |
| Generally causes modest impact on society (e.g., some school closings, encouragement of people who are sick to stay home).                                                                   | A severe pandemic could change the patterns of daily life for some time. People may choose to stay home to keep away from others who are sick. Also, people may need to stay home to care for ill family and loved ones. Travel and public gatherings could be limited. Basic services and access to supplies could be disrupted. |

A pandemic may come and go in waves, each of which can last for months at a time. Everyday life could be disrupted due to people in communities across the country becoming ill at the same time. These disruptions could include everything from school and business closings to interruption of basic services such as public transportation and health care. An especially severe influenza pandemic could lead to high levels of illness, death, social disruption, and economic loss.



## Importance and Benefits of Being Prepared

It is difficult to predict when the next influenza pandemic will occur or how severe it will be. The effects of a pandemic can be lessened if preparations are made ahead of time. When a pandemic starts, everyone around the world could be at risk. The United States has been working closely with other countries and the World Health Organization (WHO) to strengthen systems to detect outbreaks of influenza that might cause a pandemic.

A pandemic would touch every aspect of society, and so every aspect of society must begin to prepare. State, tribal, and local governments are developing, improving, and testing their plans for an influenza pandemic. Businesses, schools, universities, and other community organizations are preparing plans as well.

As you begin your individual or family planning, you may want to review your State's planning efforts and those of your local public health and emergency preparedness officials. Many of the State plans and other planning information can be found at [www.pandemicflu.gov](http://www.pandemicflu.gov).

The Department of Health and Human Services (HHS) and other Federal agencies are providing funding, advice, and other support to your State. The Federal Government will provide up-to-date information and guidance to the public if an influenza pandemic unfolds. For reliable, accurate, and timely information, visit the Federal Government's official website at [www.pandemicflu.gov](http://www.pandemicflu.gov).

The benefits of preparation will be many. States and communities will be better prepared for any disaster. Preparation will bring peace of mind and the confidence that we are ready to fight an influenza pandemic.

## Pandemic Influenza - Challenges and Preparation

As you plan, it is important to think about the challenges that you might face, particularly if a pandemic is severe. It may take time to find the answers to these challenges. The following are some situations that could be caused by a severe pandemic and possible ways to address them. A series of checklists have been prepared to help guide those efforts, to organize our national thinking, and bring consistency to our efforts. You will find two checklists (Pandemic Flu Planning Checklist for Individuals and Families; Family Emergency Health Information Sheet) to help you plan at [www.pandemicflu.gov](http://www.pandemicflu.gov).

### *Social Disruption May Be Widespread*

- Plan for the possibility that usual services may be disrupted. These could include services provided by hospitals and other health care facilities, banks, stores, restaurants, government offices, and post offices.
- Prepare backup plans in case public gatherings, such as volunteer meetings and worship services, are canceled.
- Consider how to care for people with special needs in case the services they rely on are not available.

### *Being Able to Work May Be Difficult or Impossible*

- Find out if you can work from home.

*Appendix A*

---

- Ask your employer about how business will continue during a pandemic. (A Business Pandemic Influenza Planning Checklist is available at [www.pandemicflu.gov](http://www.pandemicflu.gov).)
- Plan for the possible reduction or loss of income if you are unable to work or your place of employment is closed.
- Check with your employer or union about leave policies.

*Schools May Be Closed for an Extended Period of Time*

- Help schools plan for pandemic influenza. Talk to the school nurse or the health center. Talk to your teachers, administrators, and parent-teacher organizations.
- Plan home learning activities and exercises. Have materials, such as books, on hand. Also plan recreational activities that your children can do at home.
- Consider childcare needs.

*Transportation Services May Be Disrupted*

- Think about how you can rely less on public transportation during a pandemic. For example, store food and other essential supplies so you can make fewer trips to the store.
- Prepare backup plans for taking care of loved ones who are far away.
- Consider other ways to get to work, or, if you can, work at home.

*People Will Need Advice and Help at Work and Home*

- Think about what information the people in your workplace will need if you are a manager. This may include information about insurance, leave policies, working from home, possible loss of income, and when not to come to work if sick. (A Business Pandemic Influenza Planning Checklist is available at [www.pandemicflu.gov](http://www.pandemicflu.gov).)
- Meet with your colleagues and make lists of things that you will need to know and what actions can be taken.
- Find volunteers who want to help people in need, such as elderly neighbors, single parents of small children, or people without the resources to get the medical help they will need.
- Identify other information resources in your community, such as mental health hotlines, public health hotlines, or electronic bulletin boards.
- Find support systems-people who are thinking about the same issues you are thinking about. Share ideas.

*Be Prepared*

Stock a supply of water and food. During a pandemic you may not be able to get to a store. Even if you can get to a store, it may be out of supplies. Public waterworks services may also be interrupted. Stocking supplies can be useful in other types of emergencies, such as power outages and disasters. Store foods that:

- are nonperishable (will keep for a long time) and don't require refrigeration.
- are easy to prepare in case you are unable to cook.
- require little or no water, so you can conserve water for drinking.

*Stay Healthy*

Take common-sense steps to limit the spread of germs. Make good hygiene a habit.

- Wash hands frequently with soap and water.
- Cover your mouth and nose with a tissue when you cough or sneeze.
- Put used tissues in a waste basket.
- Cough or sneeze into your upper sleeve if you don't have a tissue.
- Clean your hands after coughing or sneezing. Use soap and water or an alcohol-based hand cleaner.
- Stay at home if you are sick.

*It is always a good idea to practice good health habits.*

- Eat a balanced diet. Be sure to eat a variety of foods, including plenty of vegetables, fruits, and whole grain products. Also include low-fat dairy products, lean meats, poultry, fish, and beans. Drink lots of water and go easy on salt, sugar, alcohol, and saturated fat.
- Exercise on a regular basis and get plenty of rest.

*Will the seasonal flu shot protect me against pandemic influenza?*

- No, it won't protect you against pandemic influenza. But flu shots can help you to stay healthy.
- Get a flu shot to help protect yourself from seasonal influenza.
- Get a pneumonia shot to prevent secondary infection if you are over the age of 65 or have a chronic illness such as diabetes or asthma.
- Make sure that your family's immunizations are up-to-date.

*Get Informed*

- Knowing the facts is the best preparation. Identify sources you can count on for reliable information. If a pandemic occurs, having accurate and reliable information will be critical.
- Reliable, accurate, and timely information is available at **[www.pandemicflu.gov](http://www.pandemicflu.gov)**.
- Another source for information on pandemic influenza is the Centers for Disease Control and Prevention (CDC) Hotline at: 1-800-CDC-INFO (1-800-232-4636). This line is available in English and Spanish, 24 hours a day, 7 days a week.
- Look for information on your local and State government websites. Links are available to each State department of public health at **[www.pandemicflu.gov](http://www.pandemicflu.gov)**.
- Listen to local and national radio, watch news reports on television, and read your newspaper and other sources of printed and web-based information.
- Talk to your local health care providers and public health officials.

**Pandemic Influenza - Prevention and Treatment**

You have an essential role in preparing and making sure you are informed of prevention activities in your local area. Each community must have plans, each State and each agency of the Federal Government

*Appendix A*

---

must work together. The Federal Government is working to boost our international and domestic disease monitoring, rebuild our vaccine industry, build stockpiles of medicines, and support research into new treatments and medicines. Your State will be taking steps to monitor and build supplies too.

*Vaccine*

Influenza vaccines are designed to protect against specific influenza viruses. While there is currently no pandemic influenza in the world, the Federal Government is making vaccines for several existing bird influenza viruses that may provide some protection should one of these viruses change and cause an influenza pandemic. A specific pandemic influenza vaccine cannot be produced until a pandemic influenza virus strain emerges and is identified. Once a pandemic influenza virus has been identified, it will likely take 4-6 months to develop, test, and begin producing a vaccine.

Efforts are being made to increase vaccine-manufacturing capacity in the United States so that supplies of vaccines would be more readily available. In addition, research is underway to develop new ways to produce vaccines more quickly.

*Treatment*

A number of antiviral drugs are approved by the U.S. Food and Drug Administration to treat and sometimes prevent seasonal influenza. Some of these antiviral medications may be effective in treating pandemic influenza. These drugs may help prevent infection in people at risk and shorten the duration of symptoms in those infected with influenza. However, it is unlikely that antiviral medications alone would effectively contain the spread of pandemic influenza. The Federal Government is stockpiling antiviral medications that would most likely be used in the early stages of an influenza pandemic. There are efforts to find new drugs and to increase the supply of antiviral medications. Antiviral medications are available by prescription only and not over the counter.

**Questions and Answers***Will bird flu cause the next influenza pandemic?*

Avian influenza (bird flu) is a disease of wild and farm birds caused by influenza viruses. Bird flu viruses do not usually infect humans, but since 1997 there have been a number of confirmed cases of human infection from bird flu viruses. Most of these resulted from direct or close contact with infected birds (e.g., domesticated chickens, ducks, turkeys).

The spread of bird flu viruses from an infected person to another person has been reported very rarely and has not been reported to continue beyond one person. A worldwide pandemic could occur if a bird flu virus were to change so that it could easily be passed from person to person. Experts around the world are watching for changes in bird flu viruses that could lead to an influenza pandemic.

*Is it safe to eat poultry?*

Yes, it is safe to eat properly cooked poultry. Cooking destroys germs, including the bird flu virus. The United States bans imports of poultry and poultry products from countries where bird flu has been found.

Guidelines for the safe preparation of poultry include the following:

- Wash hands before and after handling food.
- Keep raw poultry and its juices away from other foods.
- Keep hands, utensils, and surfaces, such as cutting boards, clean.
- Use a food thermometer to ensure poultry has been fully cooked. More information on how to properly cook poultry can be found at [www.usda.gov/birdflu](http://www.usda.gov/birdflu).

*What types of birds can carry bird flu viruses?*

Wild birds can carry bird flu viruses but usually do not get sick from them. Domesticated birds (e.g., farm-raised chickens, ducks, and turkeys) can become sick with bird flu if they come into contact with an infected wild bird. Domesticated birds usually die from the disease.

*What is the U.S. Government doing to prepare for pandemic influenza?*

The U.S. Government has been preparing for pandemic influenza for several years. In November 2005, the President announced the *National Strategy for Pandemic Influenza*. Ongoing preparations include the following:

- Working with WHO and with other nations to help detect human cases of bird flu and contain an influenza pandemic, if one begins.
- Supporting the manufacturing and testing of influenza vaccines, including finding more reliable and quicker ways to make large quantities of vaccines.
- Developing a national stockpile of antiviral drugs to help treat and control the spread of disease.
- Supporting the efforts of Federal, State, tribal, and local health agencies to prepare for and respond to pandemic influenza.
- Working with Federal agencies to prepare and to encourage communities, businesses, and organizations to plan for pandemic influenza.

## APPENDIX B

### Glossary of Terms

For the purposes of the National Pandemic Influenza Implementation Plan (Plan):

#### Acronyms

|       |                                                                                 |
|-------|---------------------------------------------------------------------------------|
| AHPA  | Animal Health Protection Act                                                    |
| AIDS  | Acquired immunodeficiency syndrome                                              |
| APEC  | Asia Pacific Economic Cooperation Forum                                         |
| APHIS | Animal and Plant Health Inspection Service                                      |
| ASEAN | Association of Southeast Asian Nations                                          |
| ATF   | Bureau of Alcohol, Tobacco, Firearms, and Explosives                            |
| ATSA  | Aviation and Transportation Security Act                                        |
| CBO   | Community-based organization                                                    |
| CBP   | Customs and Border Protection                                                   |
| CDC   | Centers for Disease Control and Prevention                                      |
| CFR   | Code of Federal Regulations                                                     |
| CIP   | Critical infrastructure protection                                              |
| CITES | Convention on International Trade in Endangered Species of Wild Fauna and Flora |
| CONUS | Continental United States                                                       |
| COOP  | Continuity of operations                                                        |
| DEA   | Drug Enforcement Administration                                                 |
| DHS   | Department of Homeland Security                                                 |
| DOC   | Department of Commerce                                                          |
| DOD   | Department of Defense                                                           |
| DOE   | Department of Energy                                                            |
| DOI   | Department of the Interior                                                      |
| DOJ   | Department of Justice                                                           |
| DOL   | Department of Labor                                                             |
| DOS   | Department of State                                                             |
| DOT   | Department of Transportation                                                    |
| DPA   | Defense Production Act                                                          |
| EIP   | Emerging Infections Program                                                     |
| EIS   | Epidemic Intelligence Service                                                   |
| EMAC  | Emergency Management Assistance Compact                                         |

*Appendix B - Glossary of Terms*

---

|          |                                                                                                                                          |
|----------|------------------------------------------------------------------------------------------------------------------------------------------|
| EMS      | Emergency Medical Services                                                                                                               |
| EMTALA   | Emergency Medical Treatment and Active Labor Act                                                                                         |
| EPA      | Environmental Protection Agency                                                                                                          |
| ESA      | Endangered Species Act                                                                                                                   |
| ESAR-VHP | Emergency System for the Advanced Registration of Volunteer Health Professionals                                                         |
| ESF      | Emergency Support Function                                                                                                               |
| ESF #1   | Emergency Support Function #1 - Transportation                                                                                           |
| ESF #8   | Emergency Support Function #8 - Public Health and Medical Services                                                                       |
| ESF #11  | Emergency Support Function #11 - Agriculture and Natural Resources                                                                       |
| ESF #13  | Emergency Support Function #13 - Public Safety and Security                                                                              |
| ESSENCE  | Electronic Surveillance System for Early Notification of Community-based Epidemics                                                       |
| FAA      | Federal Aviation Administration                                                                                                          |
| FAMS     | Federal Air Marshal Service                                                                                                              |
| FAO      | United Nations Food and Agriculture Organization                                                                                         |
| FBI      | Federal Bureau of Investigation                                                                                                          |
| FBO      | Faith-based organization                                                                                                                 |
| FDA      | Food and Drug Administration                                                                                                             |
| FEMA     | Federal Emergency Management Agency                                                                                                      |
| FHWA     | Federal Highway Administration                                                                                                           |
| FMCSA    | Federal Motor Carrier Safety Administration                                                                                              |
| FMS      | Federal medical station                                                                                                                  |
| FOAA     | Federal Operations, Export Financing, and Related Programs Appropriations Act                                                            |
| FPC      | Federal Preparedness Circular                                                                                                            |
| FRA      | Federal Railroad Administration                                                                                                          |
| FWA      | Fish and Wildlife Act                                                                                                                    |
| G-8      | Group of Eight (major industrialized nations) including the United States, France, Italy, Germany, Japan, United Kingdom, Canada, Russia |
| GEIS     | Global Emerging Infections Surveillance and Response System                                                                              |
| GHSAG    | Global Health Security Action Group                                                                                                      |
| GOARN    | Global Outbreak Alert and Response Network                                                                                               |
| HAvBED   | National Hospital Available Beds for Emergencies and Disasters                                                                           |
| HCA      | Humanitarian and Civic Assistance                                                                                                        |
| HHS      | Department of Health and Human Services                                                                                                  |
| HIPAA    | Health Insurance Portability and Accountability Act                                                                                      |
| HPAI     | Highly pathogenic avian influenza                                                                                                        |
| HSC      | Homeland Security Council                                                                                                                |



---

|        |                                                           |
|--------|-----------------------------------------------------------|
| HSPD-5 | Homeland Security Presidential Directive 5                |
| HSPD-7 | Homeland Security Presidential Directive 7                |
| HSPD-8 | Homeland Security Presidential Directive 8                |
| ICAO   | International Civil Aviation Organization                 |
| ICLN   | Integrated Consortium of Laboratory Networks              |
| ICU    | Intensive care unit                                       |
| IFI    | International financial institution                       |
| IHR    | International Health Regulations                          |
| IMO    | International Maritime Organization                       |
| IPAPI  | International Partnership on Avian and Pandemic Influenza |
| LBMS   | Live bird marketing system                                |
| LEA    | Local education agencies                                  |
| LRN    | Laboratory Response Network                               |
| MARAD  | Maritime Administration                                   |
| MBTA   | Migratory Bird Treaty Act                                 |
| MDB    | Multilateral development banks                            |
| MTF    | Medical treatment facility                                |
| NAHLN  | National Animal Health Laboratory Network                 |
| NAMRU  | Naval Medical Research Unit                               |
| NBIS   | National Biosurveillance Integration System               |
| NDMS   | National Disaster Medical System                          |
| NEC    | National Economic Council                                 |
| NGO    | Non-governmental organization                             |
| NHTSA  | National Highway Traffic Safety Administration            |
| NIMS   | National Incident Management System                       |
| NPIP   | National Poultry Improvement Program                      |
| NRC    | Nuclear Regulatory Commission                             |
| NRP    | National Response Plan                                    |
| NSC    | National Security Council                                 |
| NVS    | National Veterinary Stockpile                             |
| NVSL   | National Veterinary Services Laboratories                 |
| NVSN   | New Vaccine Surveillance Network                          |
| NWHC   | National Wildlife Health Center                           |
| OCONUS | Outside the continental United States                     |
| OHDCA  | Overseas Humanitarian, Disaster, and Civic Aid            |

---

*Appendix B - Glossary of Terms*

---

|             |                                                                                                 |
|-------------|-------------------------------------------------------------------------------------------------|
| OIE         | World Organization for Animal Health (formerly named the “Office International des Epizooties”) |
| OPM         | Office of Personnel Management                                                                  |
| Partnership | International Partnership on Avian and Pandemic Influenza                                       |
| PHEO        | Public Health Emergency Officer                                                                 |
| PHS         | U.S. Public Health Service                                                                      |
| PHSA        | Public Health Service Act                                                                       |
| PHSBPR      | Public Health Security and Bioterrorism Preparedness and Response Act                           |
| PPE         | Personal protective equipment                                                                   |
| PPIA        | Poultry Products Inspection Act                                                                 |
| PSAP        | Public safety answering point                                                                   |
| REDI        | Regional Emerging Disease Intervention Center in Singapore                                      |
| RT-PCR      | Reverse transcriptase - polymerase chain reaction                                               |
| SAFETEA-LU  | Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users            |
| SARS        | Severe acute respiratory syndrome                                                               |
| SCHIP       | State Children’s Health Insurance Program                                                       |
| SLEP        | Shelf Life Extension Program                                                                    |
| SNS         | Strategic National Stockpile                                                                    |
| SPN         | Sentinel Provider Network                                                                       |
| SPP         | Security and Prosperity Partnership                                                             |
| STB         | Surface Transportation Board                                                                    |
| TIGR        | The Institute for Genomic Research                                                              |
| Treasury    | Department of the Treasury                                                                      |
| TSA         | Transportation Security Administration                                                          |
| UN          | United Nations                                                                                  |
| USACE       | U.S. Army Corps of Engineers                                                                    |
| USAID       | U.S. Agency for International Development                                                       |
| USCG        | U.S. Coast Guard                                                                                |
| USDA        | Department of Agriculture                                                                       |
| USTR        | U.S. Trade Representative                                                                       |
| VA          | Department of Veterans Affairs                                                                  |
| VHA         | Veterans Health Administration                                                                  |
| WHO         | World Health Organization                                                                       |

**Definition of Terms**

**Adjuvants.** Substances that can be added to a vaccine to increase the effectiveness of the vaccine.

**Affected country.** An at-risk country experiencing endemic (widespread and recurring) or epidemic (isolated) cases in humans or domestic animals of influenza with human pandemic potential.

**Antiviral medications.** Medications presumed to be effective against potential pandemic influenza virus strains. These antiviral medications include the neuraminidase inhibitors oseltamivir (Tamiflu®) and zanamivir (Relenza®).

**Arrival screening.** Medical screening upon arrival to detect individuals who have signs of illness or who are at high risk of developing illness.

**Asymptomatic.** Asymptomatic means without symptoms of influenza.

**At-risk country.** An unaffected country with insufficient medical, public health, or veterinary capacity to prevent, detect, or contain influenza with pandemic potential.

**Colleges.** Educational institutions post 12th grade (post high school).

**Community-based organization.** A private nonprofit organization, Indian tribe or tribally sanctioned organization, or other type of group that works within a community for the improvement of some aspect of that community. Community-based organizations include non-profit organizations (501 c(3)), faith-based organizations, tribes, and their subsidiaries.

**Containment.** Contain an outbreak to the affected region(s) and limit of spread of the pandemic through aggressive attempts to contain.

**Continuity of operations.** Refers to the capability to ensure the performance of essential functions during any emergency or situation that may disrupt normal operations.

**Cough etiquette.** Covering ones mouth and nose while coughing or sneezing; using tissues and disposing in no-touch receptacles; and washing your hands to avoid spreading an infection to others.

**Countermeasures.** Refers to pre-pandemic and pandemic influenza vaccine and antiviral medications.

**Critical infrastructure.** Systems and assets, whether physical or virtual, so vital to the United States that the incapacity or destruction of such systems and assets would have a debilitating impact on security, national economic security, national public health or safety, or any combination of those matters. Specifically, it refers to the critical infrastructure sectors and key resources identified in Homeland Security Presidential Directive 7 (HSPD-7). As defined by HSPD-7, critical infrastructure includes the following sectors and key resources: agriculture and food; public health and health care; drinking water and water treatment systems; energy (including the production, refining, storage, and distribution of oil and gas, and electric power except for nuclear facilities); banking and finance; national monuments and icons; defense industrial base; information technology; telecommunications; chemical; transportation systems (including mass transit, aviation, maritime, ground/surface, and rail and pipeline systems); emergency services; postal and shipping; dams; government facilities; commercial facilities; and nuclear reactors, material, and waste. Critical infrastructure in this Plan is used to refer to the 17 critical infrastructure and key resources included in the National Infrastructure Protection Plan.

**Delegation of authority.** Identification, by position, the authorities for making policy determinations and decisions at headquarters, field levels, and other organizational locations, as appropriate. Generally, pre-determined delegations of authority will take effect when normal channels of direction are disrupted and terminate when these channels have resumed.

**Departure screening.** Medical screening prior to departure from a high-risk area to identify individuals who have signs of illness (influenza) or who are at high risk of developing illness.

**Devolution.** The capability to transfer and sustain authority and responsibility for essential functions from an organization's primary operating staff and facilities, to other employees and facilities.

**Disaggregation of disease transmission networks.** The disruption of activities and social interactions that facilitate transmission of influenza (e.g., closure of schools, canceling public meetings or large social gatherings, keeping schoolchildren home, and restriction of travel).

**Domestic animals.** Livestock, including poultry, and other farmed birds or mammals; does not include companion animals such as dogs, cats, or pet birds.

**Dose sparing strategies.** Strategies to increase influenza vaccine immunogenicity and minimize the dose of vaccine necessary to confer immunity.

**En route screening.** Surveillance (typically by non-medical personnel) to detect individuals who develop signs of illness (influenza) while en route.

**Epidemic.** A pronounced clustering of cases of disease within a short period of time; more generally, a disease whose frequency of occurrence is in excess of the expected frequency in a population during a given time interval.

**ESAR-VHP.** Emergency System for Advance Registration of Volunteer Health Professionals.

**Essential functions.** Functions that are absolutely necessary to keep a business operating during an influenza pandemic, and critical to survival and recovery.

**Face mask.** Disposable surgical or procedure face mask (see definitions of both below).

**Faith-based organization.** Any organization that has a faith-inspired interest.

**Geographic quarantine (cordon sanitaire).** The isolation, by force if necessary, of localities with documented disease transmission from localities still free of infection.

**Hand hygiene.** Hand washing with either plain soap or antimicrobial soap and water and use of alcohol-based products (gels, rinses, foams) containing an emollient that do not require the use of water.

**High-throughput rapid diagnostic kit.** Medical technology to accurately and rapidly detect influenza strains. The technology is currently being used to rapidly detect avian influenza employing nucleic acid diagnostic primers (short strands of DNA/RNA).

**High-risk country.** An at-risk country that is located in proximity to an affected country, or in which a wildlife case of influenza with pandemic potential has been detected.

**Highly pathogenic avian influenza (HPAI).** An infection of poultry caused by any influenza A virus that meets the World Organization for Animal Health (OIE) definition for high pathogenicity based on the mortality rate of chickens exposed to the virus intravenously or on the amino acid sequence of the cleavage site of the virus' hemagglutinin molecule.

**Installations.** Refers to military posts, installation, bases, stations, and activities.

**International financial institution.** Usually refers to intergovernmental organizations dealing with financial issues, most often the International Monetary Fund and/or the World Bank.

**International Partnership for Avian and Pandemic Influenza (the Partnership; IPAPI).** Partnership announced by President Bush at the UN General Assembly on September 14, 2005. Over 80 countries and 8 international organizations are working in the Partnership to fight pandemic influenza nationally and globally.

**Isolation.** Separation of infected individuals from those who are not infected.

**Key assets.** Subset of key resources that are "individual targets whose destruction could cause large scale injury, death, or destruction of property, and/or profoundly damage our national prestige or confidence."

**Key resources.** Publicly or privately controlled resources essential to the minimal operations of the economy and government. This refers to the four key resources identified in HSPD-7 and the National Infrastructure Protection Plan. These four key resources include: dams; government facilities; commercial facilities; and nuclear reactors, material, and waste.

**Laboratory Response Network.** National network of local, State, and Federal public health, food testing, veterinary diagnostic, and environmental testing laboratories supported by CDC that provide the laboratory infrastructure and capacity to respond to biological and chemical terrorism, and other public health emergencies.

**Layered protective measures.** Rather than focusing on a single measure for mitigation, a layered approach uses an array of measures deployed in tandem, to reduce overall risk. A layered, system-wide, integrated approach to risk reduction includes redundant measures and is designed to avoid a single point of failure. Examples include, implementing pre-departure, en route, and arrival screening measures for international travel.

**Live bird marketing system (LBMS).** Live poultry markets in the United States and the poultry distributors and poultry production premises that supply those markets.

**Local education agencies (LEAs).** Local (State, county, city, district) school boards.

**Localities.** Refers to local (county, city, municipal) governments and agencies.

**Multilateral development banks.** Multilateral development banks are institutions that provide financial support and professional advice for economic and social development activities in developing countries.

**National Animal Health Laboratory Network (NAHLN).** Refers to a cooperative effort among the American Association of Veterinary Laboratory Diagnosticians, the USDA Animal and Plant Health Inspection Service, and the USDA Cooperative State Research, Education and Extension Service to coordinate the capabilities of Federal, State, and university veterinary diagnostic laboratories to enhance the response to animal health events.

**National Poultry Improvement Plan (NPIP).** Cooperative industry-State-Federal program that establishes standards for the evaluation of poultry with respect to freedom from certain diseases.

**National veterinary services.** The national veterinary administration, all the veterinary authorities, and all persons authorized, registered, or licensed by the veterinary statutory body of a country to prevent and/or control animal diseases.

**National Veterinary Stockpile (NVS).** Refers to the supply of materiel, including vaccine, that is appropriate for a response to a damaging animal disease and capable of deployment within 24 hours of an outbreak; the stockpile is maintained by USDA's Animal and Plant Health Inspection Service.

**Orders of succession.** Refers to the sequential order or ranking of individuals who would assume authority and responsibility if the leadership is incapacitated or unavailable.

**Outbreak.** An epidemic limited to localized increase in the incidence of disease, e.g., in a village, town, or closed institution; a cluster of cases of an infectious disease.

**Outbreak containment.** Disruption of epidemic amplification through the use of medical countermeasures and infection control techniques; "containment" also refers more generally to delaying the geospatial spread of an epidemic.

**Pandemic.** A worldwide epidemic when a new or novel strain of influenza virus emerges in which humans have little or no immunity, and develops the ability to infect and be passed between humans.

**Pandemic vaccine.** Vaccine for specific influenza virus strain that has evolved the capacity for sustained and efficient human-to-human transmission. This vaccine can only be developed once the pandemic strain emerges.

**Pathogenicity.** Refers to the condition or quality of being pathogenic, or the ability to cause disease.

**Plan.** Refers to the Implementation Plan for the National Strategy for Pandemic Influenza.

**Post-exposure prophylaxis.** The use of antiviral medications in individuals exposed to others with influenza to prevent disease transmission.

**Pre-pandemic vaccine.** Vaccine against strains of influenza virus in animals that have caused isolated infections in humans of pandemic potential. This vaccine is prepared prior to the emergence of a pandemic strain and may be a good or poor match (and hence of greater or lesser protection) for the pandemic strain that ultimately emerges.

**Priority country.** A priority country is a high-risk or affected country that merits special attention because of the severity of the outbreak, its strategic importance, its regional role, or foreign policy priorities.

**Procedure mask.** Disposable face mask that is either flat or pleated and is affixed to the head with ear loops.

**Prophylaxis.** Prevention of disease or of a process that can lead to disease. With respect to pandemic influenza this specifically refers to the administration of antiviral medications to healthy individuals for the prevention of influenza.

**Quarantine.** Separation of individuals who have been exposed to an infection but are not yet ill from others who have not been exposed to the transmissible infection.

**Rapid diagnostic test.** Medical test for rapidly confirming the presence of infection with a specific influenza strain.

**Reconstitution.** Refers to the process by which an organization resumes normal operations.

**Respirator.** Refers to a particulate respirator, commonly known as N-95 respirator, often used in hospitals to protect against infectious agents. Particulate respirators are “air-purifying respirators” because they clean particles out of the air as one breathes.

**$R_0$ .** Represents the basic reproductive rate of a pathogen, i.e., the average number of secondary infections caused by an infected individual within a given social context. An  $R_0 = 2$  means that infected individuals, on average, transmit infection to two other people, so that every generation of disease transmission doubles the number of people infected.  $R_0$  will change during an epidemic as public health interventions are applied, the behavior of individuals changes, and as the pool of persons susceptible to the disease is depleted.

**Schools (K-12).** Refers to schools, both public and private, spanning the grades kindergarten through 12th grade (elementary through high school).

**Sector.** Part or division of the national economy.

**Sector-Specific Agency.** Federal departments and agencies identified under HSPD-7 as responsible for infrastructure protection activities in a designated critical infrastructure sector or key resources category.

**Situational awareness.** Situational awareness is the ability to identify, process, and comprehend the critical elements of information about what is happening during an evolving influenza pandemic.

**Snow days.** Refers to days which the authorities recommend that individuals and families limit social contacts by remaining within their households to reduce community disease transmission of infection.

**Social distancing.** Infection control strategies that reduce the duration and/or intimacy of social contacts and thereby limit the transmission of influenza. There are two basic categories of intervention: transmission interventions, such as the use of facemasks, may reduce the likelihood of casual social contacts resulting in disease transmission; contact interventions, such as closing schools or canceling large gatherings, eliminate or reduce the likelihood of contact with infected individuals.

**Standard of care.** The level of care that is reasonably expected under the extant circumstances.

**States.** Refers to State governments and State agencies.

**Strategy.** Refers to the *National Strategy for Pandemic Influenza*.

**Surge capacity.** Refers to the ability to expand provision of services beyond normal capacity to meet transient increases in demand. Surge capacity within a medical context denotes the ability of health care or laboratory facilities to provide care or services above their usual capacity, or to expand manufacturing capacity of essential medical materiel (e.g., vaccine) to meet increased demand.



**Surgical mask.** Refers to disposable face masks that comes in two basic types: one type is affixed to the head with two ties, conforms to the face with the aid of a flexible adjustment to the nose bridge, and may be flat/pleated or duck-billed in shape; the second type of surgical mask is pre-molded, adheres to the head with a single elastic and has a flexible adjustment for the nose bridge.

**Symptomatic.** Symptomatic means with symptoms of influenza.

**Targeted passenger travel restrictions.** Travel restrictions to the United States targeting travelers from a high-risk area or from areas unable to meet U.S. criteria for departure and en route screening.

**Telecommuting.** Working from home or an alternate site and avoiding coming to the workplace through telecommunication (computer access).

**Telework.** Refers to the activity of working away (home) from the workplace through telecommunication (computer access).

**$T_g$ .** Generation time of a pathogen, or how long it takes for infected individuals to infect others. Epidemics caused by a pathogen with an  $R_0 = 2$  and a  $T_g = 2$  days will double in size about every 2 days, epidemics caused by a pathogen with an  $R_0 = 3$  and a  $T_g = 9$  days will triple in size about every 9 days, etc.

**Treatment course (antiviral medications).** The course of antiviral medication prescribed as treatment (not prophylaxis) for a person infected with an agent susceptible to the antiviral medication. For oseltamivir, a treatment course for seasonal influenza is 10 capsules, administered twice daily for 5 days (a prophylaxis course is much greater, typically 42 capsules taken once daily for 42 days).

**Treatment course (vaccine).** The course of vaccine (typically two injections) required to induce protective immunity against the target of the vaccine.

**TRICARE.** Department of Defense's worldwide health care program for active duty and retired uniformed services members and their families.

**Universities.** Refers to educational institutions post 12th grade (post high school).

**U.S. travelers from affected areas.** U.S. citizens traveling to the United States from countries or region where an outbreak (influenza pandemic) has occurred.

**Virulence.** Virulence refers to the disease-evoking severity of influenza.

**Wave.** The period during which an outbreak or epidemic occurs either within a community or aggregated across a larger geographical area. The disease wave includes the time during which disease occurrence increases rapidly, peaks, and declines back toward baseline.

## APPENDIX C

### Authorities and References

Various Federal statutes, regulations, orders, directives, and plans authorize or otherwise enable Federal departments and agencies to engage in actions to support the three pillars of the *National Strategy for Pandemic Influenza (Strategy)*: Preparedness and Communication; Surveillance and Detection; and Response and Containment. The major statutes, regulations, directives, and plans discussed in this Implementation Plan (Plan) are those summarized below.<sup>23</sup>

### Chapter 2 - U.S. Government Planning for a Pandemic

**Executive Order 12656, Assignment of Emergency Preparedness Responsibilities** (November 18, 1988). This Executive Order assigns responsibilities to each Federal agency for national security and emergency preparedness.

**Homeland Security Presidential Directive 5 (HSPD-5) Management of Domestic Incidents** (February 28, 2003). This Presidential Directive is intended to enhance the ability of the United States to manage domestic incidents by establishing a single, comprehensive national incident management system. In HSPD-5 the President designates the Secretary of Homeland Security as the Principal Federal Official for Domestic Incident Management and empowers the Secretary to coordinate Federal resources used in response to or recovery from terrorist attacks, major disasters, or other emergencies in specific cases. The directive assigns specific responsibilities to the Attorney General, Secretary of Defense, Secretary of State, and the Assistants to the President for Homeland Security and National Security Affairs, and directs the heads of all Federal departments and agencies to provide their “full and prompt cooperation, resources, and support,” as appropriate and consistent with their own responsibilities for protecting national security, to the Secretary of Homeland Security, Attorney General, Secretary of Defense, and Secretary of State in the exercise of leadership responsibilities and missions assigned under HSPD-5. The directive also notes that it does not alter, or impede the abilities of Federal departments and agencies to carry out their responsibilities under law.

**National Response Plan (NRP)**. In HSPD-5, the President directed the development of a new NRP to align Federal coordination structures, capabilities, and resources into a unified, all-discipline, and all-hazards approach to domestic incident management. The NRP, released in December 2004 and fully implemented in April 2005, is such a plan. It provides the structure and mechanisms for the coordination of Federal support to State, local, and tribal incident managers and for exercising direct Federal authorities and responsibilities. The NRP assists in the important homeland security mission of preventing terrorist attacks within the United States; reducing the vulnerability to all natural and manmade hazards; and minimizing the damage and assisting in the recovery from any type of incident that occurs.

### Chapter 3 - Federal Government Response to a Pandemic

**The Economy Act**, 31 U.S.C. §§ 1535-1536 (2002). The Economy Act authorizes Federal agencies to provide goods or services on a reimbursable basis to other Federal agencies when more specific statutory authority to do so does not exist.

<sup>23</sup> Some of the authorities and references described in this appendix are applicable to actions discussed in more than one chapter but may only be set forth in the section they are primarily applicable to.

**Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1974**, codified as amended at 42 U.S.C. §§ 5121-5206, and scattered sections of 12 U.S.C., 16 U.S.C., 20 U.S.C., 26 U.S.C., 38 U.S.C. (2002). The Stafford Act establishes programs and processes for the Federal Government to provide disaster and emergency assistance to States, local governments, tribal nations, individuals, and qualified private nonprofit organizations. The provisions of the Stafford Act are broad and may cover many situations, including natural disasters and terrorist events. In a major disaster or emergency as defined in the Stafford Act, the President “may direct any Federal agency, with or without reimbursement, to utilize its authorities and the resources granted to it under Federal law (including personnel, equipment, supplies, facilities, and managerial, technical, and advisory services) in support of State and local assistance efforts.”

Under the Act, the Federal Emergency Management Agency (FEMA) of the Department of Homeland Security (DHS), is authorized to coordinate the activities of Federal agencies in response to a Presidential declaration of a major disaster or emergency, if warranted, with the Department of Health and Human Services (HHS) having the lead for health and medical services. The President could declare either an emergency or a major disaster with respect to an influenza pandemic.

**The National Emergencies Act**, 50 U.S.C. §§ 1601-1651 (2003), establishes procedures for Presidential declaration and termination of national emergencies. The act requires the President to identify the specific provision of law under which he or she will act in dealing with a declared national emergency and contains a sunset provision requiring the President to renew a declaration of national emergency to prevent its automatic expiration. The Presidential declaration of a national emergency under the act is a prerequisite to exercising any special or extraordinary powers authorized by statute for use in the event of national emergency.

**The Defense Production Act (DPA) of 1950**, codified as amended by the Defense Production Act Reauthorization of 2003 at 50 U.S.C. app. §§ 2061-2171 (2002), is the primary authority to ensure the timely availability of resources for national defense and civil emergency preparedness and response. Among other things, the DPA authorizes the President to demand that companies accept and give priority to government contracts that the President “deems necessary or appropriate to promote the national defense.” The DPA defines “national defense” to include critical infrastructure protection and restoration, as well as activities authorized by the emergency preparedness sections of the Stafford Act. Consequently, DPA authorities are available for activities and measures undertaken in preparation for, during, or following a natural disaster or accidental or man-caused event. The President’s authority has been delegated to various agencies, depending on the product, with the Department of Commerce (DOC) providing overall coordination of the Defense Priorities and Allocations System. The DOC has redelegated DPA authority under Executive Order 12919, National Defense Industrial Resource Preparedness (June 7, 1994), as amended, to the Secretary of Homeland Security to place and, upon application, to authorize State and local governments to place priority-rated contracts in support of Federal, State, and local emergency preparedness activities.

**The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PHSBPR)**, Pub. L. No. 107-188, 116 Stat. 294 (2002) (codified in scattered sections of 7 U.S.C., 18 U.S.C., 21 U.S.C., 29 U.S.C., 38 U.S.C., 42 U.S.C., and 47 U.S.C. (2002)), is designed to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies. Key provisions of the PHSBPR, 42 U.S.C. §§ 247d and 300hh among others, address the development of a national preparedness plan by HHS designed to provide effective assistance to State and local governments in the event of bioterrorism or other public health emergencies; operation of the National Disaster Medical

System (NDMS) to mobilize and address public health emergencies; grant programs for the education and training of public health professionals and improving State, local, and hospital preparedness for and response to bioterrorism and other public health emergencies; streamlining and clarifying communicable disease quarantine provisions; enhancing controls on dangerous biological agents and toxins; and protecting the safety and security of food and drug supplies.

**Flood Control and Coastal Emergencies Act**, 33 U.S.C § 701n (2002), authorizes the U.S. Army Corps of Engineers (USACE) to use an emergency fund for preparation for emergency response to natural disasters, flood fighting and rescue operations, rehabilitation of flood control and hurricane protection structures, temporary restoration of essential public facilities and services, advance protective measures, and provision of emergency supplies of water. The USACE receives funding for such activities under this authority from the Energy and Water Development Appropriation.

**Volunteer Services.** There are statutory exceptions to the general statutory prohibition against accepting voluntary services under 31 U.S.C. § 1342 (2002) that can be used to accept the assistance of volunteer workers. Such services may be accepted in “emergencies involving the safety of human life or the protection of property.” Additionally, provisions of the Stafford Act, 42 U.S.C. §§ 5152(a), 5170a(2) (2002), authorize the President to, with their consent, use the personnel of private disaster relief organizations and to coordinate their activities. Under the Congressional Charter of 1905, 36 U.S.C. §§ 300101-300111 (2002), the American Red Cross and its chapters are a single national corporation. The Charter mandates that the American Red Cross maintain a system of domestic and international disaster relief. The American Red Cross qualifies as a nonprofit organization under section 501(c)(3) of the Internal Revenue Code.

## Chapter 4 - International Efforts

**Clearance of Proposed International Agreements.** The Department of State (DOS) must ensure that all proposed international agreements of the United States are fully consistent with U.S. foreign policy objectives. The requirements for this coordination with and clearance from DOS are codified, in part, at sections 181.1-8 of Title 22 of the Code of Federal Regulations (CFR). The C-175 clearance requirements are specifically referenced in 22 C.F.R. § 181.4 (and Volume 11 of the Foreign Affairs Manual, Chapter 700).

**Foreign Assistance.** Relevant foreign assistance authorities for health and disasters authorize the provision of assistance “notwithstanding any other provision of law.” These authorities would permit the provision of aid, such as medical goods and services, and even security details to ensure delivery of these items. Annual foreign operations appropriations acts reenact this special health authority annually, as follows:

**Section 522 of the FY06 Foreign Operations, Export Financing, and Related Programs Appropriations Act (FOAA)**, Pub. L. No. 109-102, funds child survival and health activities and includes robust authority that would enable us to overcome any country-specific and other assistance limitations (e.g., North Korea, Iran, Burma, China). In cases of emergency to health and human welfare, there is an exceptional authority reenacted annually from the usual 15-day Congressional notification period (required for reprogramming notifications). Any assistance appropriated as economic assistance (i.e., not just funds appropriated for health) may be used pursuant to this authority to provide assistance for health.

**The Foreign Assistance Act of 1961**, as amended, provides relevant authorities for disaster assistance, with a full “notwithstanding” authority, and for health, with a more limited “notwithstanding” authority, as follows:

- FAA § 491 authorizes provision of assistance for natural and man-made disasters, “notwithstanding any other provision of law.”
- FAA §104(c) (22 U.S.C. § 2151b-4) authorizes “[a]ssistance for [h]ealth and [d]isease [p]revention.” Such assistance “may be made available notwithstanding any other provision of law that restricts assistance to foreign countries.” There are some limitations on the “notwithstanding” authority (e.g., the notwithstanding clause does not trump limitations on assistance to organizations that support or participate in a program of coercive abortion or involuntary sterilization), but we do not foresee such exceptions constraining our ability to respond to a pandemic influenza.
- Title IV of the Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Tsunami Relief, Pub. L. No. 109-13, 119 Stat. 231 (2005), appropriates \$656 million for emergency relief, rehabilitation, and reconstruction aid to countries affected by the Asian tsunami and earthquakes of December 2004 and March 2005, and the avian influenza virus, to remain available until September 30, 2006. Additional funding is being sought as part of the President’s \$7.1 billion pandemic influenza legislative request.

**Foreign Assistance to Address Civil Unrest Abroad.** If foreign assistance were required for police to address civil unrest abroad associated with an outbreak, such assistance could be provided for police forces under various authorities, most notably, under FAA § 481(a)(4). Assistance for military forces for such purposes could also be provided under certain authorities, e.g., section 551 of the FAA for peace-keeping and other programs in the national security interest of the United States and section 23 of the Arms Export Control Act codified in 22 U.S.C. § 2751 et seq. (2000) for military assistance.

**Title 11, Emergency Supplemental Appropriation to address Pandemic Influenza of the Department of Defense Appropriations Act of 2006**, Pub. L. No. 109-148 (2006). This Act provides \$10 million and additional authority for the Department of Defense (DOD) to assist military partner nations in pandemic influenza response preparedness.

**The Public Health Service Act (PHSA)**, 42 U.S.C. § 201 note (2005). The PHSA authorizes HHS to engage in international biomedical research, health care technology, and specified health services research and statistical activities “to advance the status of the health sciences in the United States” and thereby the health of the American people (42 U.S.C. 242). HHS has interpreted this authority to support numerous international surveillance and research activities as well.

**Military assistance.** The major authorities that DOD may rely on to provide assistance outside the United States, include:

- 10 U.S.C. § 401 (Humanitarian and Civic Assistance (HCA)). This section of the Code provides for HCA projects, approved in coordination with the Combatant Commanders and DOS that improve operational readiness skills of participating U.S. forces and are conducted in conjunction with military operations.
- 10 U.S.C. § 402 (Transportation). Subject to certain exceptions, DOD may transport supplies provided by non-governmental, U.S. sources without charge on a space-available basis.



- 10 U.S.C. §404 (Foreign Disaster Assistance). Under certain circumstances and subject to certain congressional notice requirements, the President may direct the Secretary of Defense to provide disaster assistance outside the United States in order to respond to manmade or natural disasters when necessary to prevent the loss of life.
- 10 U.S.C. § 2557 (Excess Nonlethal Supplies: Humanitarian Relief). This provision authorizes excess supplies to be made available to DOS for humanitarian relief. DOS will be responsible for distribution.
- 10 U.S.C. § 2561 (Transportation and Other Humanitarian Support). DOD also may provide fully funded transportation (on an other-than space-available basis), if it pays such transportation costs with its operation and maintenance funds earmarked for Overseas Humanitarian, Disaster, and Civic Aid (OHDCA) purposes.

## Chapter 5 - Transportation and Borders

### *Transportation Authorities*

**General Transportation Security Authorities.** DHS has broad authority to protect transportation security, including authorities that could keep quarantinable diseases from reaching the United States. The Transportation Security Administration (TSA) is “responsible for security in all modes of transportation” (49 U.S.C. § 114). If the TSA Assistant Secretary “determines that a regulation or security directive must be issued immediately in order to protect transportation security the [Assistant Secretary] shall issue the regulation or security directive without providing notice or an opportunity for comment and without prior approval of the Secretary [of Homeland Security]” (49 U.S.C. § 114(l)(2)(A)). TSA interprets these provisions on transportation security to provide authority for TSA to keep a flight destined for the United States from landing in the United States if it is determined that a flight may be transporting persons with a quarantinable disease. These TSA authorities are also sufficiently broad to allow TSA to direct an air carrier to temporarily avoid deplaning its passengers until HHS or other medical authorities can screen the passengers. Finally, pursuant to 49 U.S.C. § 114(q), the Federal Air Marshal Service (FAMS) of TSA has the authority to exercise law enforcement powers in the transportation domain.

**Emergency Transportation Security Authorities.** In the case of a national emergency, the Aviation and Transportation Security Act (ATSA) provides DHS with additional authorities. ATSA confers four specific national emergency responsibilities upon DHS: “(A) To coordinate domestic transportation, including aviation, rail, and other surface transportation, and maritime transportation (including port security); (B) To coordinate and oversee the transportation-related responsibilities of other departments and agencies of the Federal Government other than the DOD and the military departments; (C) To coordinate and provide notice to other departments and agencies of the Federal Government, and appropriate agencies of State and local governments, including departments and agencies for transportation, law enforcement, and border control, about threats to transportation; (D) To carry out such other duties, and exercise such other powers, related to transportation during a national emergency as the Secretary shall prescribe” (49 U.S.C. § 114(g) (1) (A)-(D)). ATSA qualifies this authority by adding: “(2) AUTHORITY OF OTHER DEPARTMENTS AND AGENCIES. The authority of the [Secretary of Homeland Security] under this subsection shall not supersede the authority of any other department or agency of the Federal Government under law with respect to transportation or transportation-related matters, whether or not during a national emergency (49 U.S.C. § 114(g) (2)). ATSA also adds: “(3) CIRCUMSTANCES. The Secretary [of Homeland Security] shall prescribe the circumstances constituting a national emergency for purposes of this subsection” (49 U.S.C. § 114(g) (3)).

During a national emergency declared by the President, the Department of Transportation (DOT), through the Maritime Administration (MARAD), can enhance U.S. sealift capacity by taking control of vessels, containers, and chassis through requisitioning (46 App. U.S.C. § 1242; 50 U.S.C. §§ 196-198).

**Aviation.** The Federal Aviation Administration (FAA) is the lead agency for aviation safety regulation and oversight and is responsible for the operation and maintenance (to include personnel, physical, and cyber) of the Air Traffic Control System (Title 49 U.S.C., subtitle VII, Aviation Programs). Any movement in the navigable airspace of the United States can be stopped, redirected, or excluded by the FAA, regardless of the commodity involved (49 U.S.C. § 44701). Additionally, the FAA can order U.S.-flag air carriers not to enter designated airspace of a foreign country (e.g., to keep airspace clear for rescue operations). If the FAA determines that an emergency exists related to safety in air commerce that requires immediate action, the FAA may prescribe regulations and issue orders immediately to meet that emergency (49 U.S.C. § 46105(c)). FAA interprets these provisions on aviation security or safety to provide authority for FAA to close airspace to, or redirect, a flight if it is determined that a flight may be transporting persons with a quarantinable disease.

Subject to the direction and control of the Secretary of Homeland Security, the TSA has the authority to cancel a flight or series of flights if a decision is made that a particular security threat cannot be addressed in a way adequate to ensure, to the extent feasible, the safety of passengers and crew (49 U.S.C. § 44905(b)). TSA is required to work in conjunction with the FAA with respect to any actions or activities that may affect aviation safety or air carrier operations (49 U.S.C. § 114(f)(13); 6 U.S.C. § 233(a)). TSA interprets these provisions to authorize TSA to cancel flights in the case of a pandemic influenza.

**Chicago Convention.** The Chicago Convention, a multilateral treaty establishing the framework for the operation of international civil aviation, provides authority to deny entry to flights that do not comply with U.S. laws and regulations, including those relating to entry, clearance, customs, and quarantine. The Chicago Convention articles that may be relevant include 11, 13, 14, 16, 29, and 89.

**Rail.** Any movement in the United States by rail carrier (including commuter rail but excluding urban rapid transit not connected to the general system of rail transportation) may be stopped, redirected, or limited by the authority of the Surface Transportation Board (STB) or the Federal Railroad Administration (FRA), or both, irrespective of commodity involved. The FRA may issue an emergency order imposing any restrictions or prohibitions necessary to abate what the FRA determines is an emergency situation involving a hazard of death or personal injury caused by unsafe conditions or practices (49 U.S.C. § 20104). For a period of 270 days, the STB may direct the movement and prioritization of freight traffic necessary to alleviate an emergency situation involving the failure of traffic movement having substantial adverse impacts on shippers or on rail service in any region of the United States (49 U.S.C. § 11123), and may also order that preference be given to certain traffic, when the President so directs in time of war or threatened war (49 U.S.C. § 11124).

**Mass Transit.** In general, DOT is forbidden from regulating the operation, routes, schedules, rates, fares, tolls, rentals, or other charges of public transportation system grantees of the Federal Transit Administration. However, the Safe, Accountable, Flexible, Efficient, Transportation Equity Act: A Legacy for Users, Pub. L. No. 109-59, 119 Stat. 1144 (2005) (SAFETEA\_LU), amended section 5334 of title 49 of the United States Code to create an express exception to the above prohibition when needed for national defense or in the event of a national or regional emergency.

**Highways.** The Federal Highway Administration (FHWA) possesses no authority to operate the Nation's highway system during times of emergency. States, local governments, and other Federal agencies own,



control, and operate the Nation's roads and bridges. The Federal Motor Carrier Safety Administration (FMCSA) can order a vehicle to cease operation and relocate to a safe place if there is reason to believe it would constitute a security threat because it carries a hazardous material (49 U.S.C. § 521(b)(5); 49 U.S.C. § 5103(b), Section 1711, Homeland Security Act of 2002, Pub. L. 107-296).

**Pipelines.** The operation of any pipeline facility used to transport gas or hazardous liquid can be stopped by the Pipeline and Hazardous Materials Safety Administration if continued operation of the facility is or would become hazardous (49 U.S.C. § 60112).

**Hazardous Materials.** Any aspect of hazardous materials transportation that presents an "imminent hazard" may be halted by court order (49 U.S.C. § 5122(b)). An "imminent hazard" is a condition that presents a substantial likelihood that death, serious illness, severe personal injury, or a substantial endangerment to health, property, or the environment may occur before the reasonable foreseeable completion date of a formal proceeding begun to lessen the risk of that death, illness, injury, or endangerment (49 U.S.C. § 5102). DOT is also authorized to issue or impose emergency restrictions, prohibitions, recalls, or out-of-service orders, without notice or an opportunity for a hearing, but only to the extent necessary to abate an imminent hazard (49 U.S.C. § 5121(d)).

**Transportation Authorities Relating Specifically to Vessels.** In the case of vessels, if there is evidence that a vessel is carrying a person or persons with a quarantinable disease that would present a public health threat to the port if the ship or the person were allowed to enter, the U.S. Coast Guard (USCG) has authority to prevent the vessel from entering a U.S. port or place until the infected person(s) can be dealt with by HHS/CDC personnel so as to prevent the spread of the disease in the United States (50 U.S.C. §§ 191–195; 33 U.S.C. §§ 1221–1232; 33 C.F.R. part 6; 33 C.F.R. § 160.111).

The Saint Lawrence Seaway Development Corporation may halt traffic through those portions of the Saint Lawrence Seaway subject to the jurisdiction of the United States, if required for safety or security of the seaway or for national security (e.g., deepwater vessels could be barred from entering or leaving the Seaway) (33 U.S.C. §§ 984, 1226).

**Defense Production Act of 1950,** 50 U.S.C. App. §§ 2061-2171 (2002). The DPA is the primary authority to ensure the timely availability of resources for national defense and civil emergency preparedness and response. Under the DPA, the Secretary of Transportation has been delegated the authority to marshal civil transportation in a defined area if national defense or domestic emergency conditions require civil transportation materials, services, or facilities that are not being provided by the marketplace. However, formal findings must be made by DOD, Department of Energy (DOE), or DHS, before DOT can exercise its DPA authority.

#### *Border Authorities*

**General Border Authorities.** DHS has broad authority to protect U.S. borders, including specific statutory provisions designating USCG and the United States Customs and Border Protection (CBP) to assist in the enforcement of State health laws and Federal quarantine regulations (42 U.S.C. §§ 97, 268). CBP has general authority pursuant to the customs and immigration laws (e.g., 19 U.S.C. §§ 482, 1461, 1496, 1589a, 1499, 1581, 1582, 1595a, and 8 U.S.C. §§ 1157, 1357) to examine merchandise, cargo, conveyances and persons upon their entry to, and exit from, the United States to ensure compliance with U.S. law, and to seize and forfeit conveyances, animals, or other things imported contrary to law or used in the unlawful importation, exportation, or subsequent transportation of articles imported contrary to U.S. law (18 U.S.C. § 545, 19 U.S.C. § 1595a). Section 421 of the Homeland Security Act transferred to the

Secretary of Homeland Security certain agricultural import and entry inspection functions originally assigned to the Secretary of Agriculture under the Animal Health Protection Act. This transfer included the authority to enforce prohibitions or restrictions on the entry of livestock diseases into the United States. Finally, the Secretary of Homeland Security and the Commissioner of CBP may temporarily close ports of entry “when necessary to respond to a national emergency or to [respond to] a specific threat to human life or national interests” (19 U.S.C. § 1318(b)). Such closings would effectively stop the legal entry of persons and conveyances and the legal importation and exportation of articles at those places.

**Border Authorities Relating to Travelers.** DHS has authority to find inadmissible any alien “who is determined (in accordance with the regulations prescribed by the Secretary of Health and Human Services) to have a communicable disease of public health significance” (8 U.S.C. § 1182(a)(1)). Under 8 U.S.C. § 1222(a), DHS could detain aliens for the purpose of determining whether they have a communicable disease listed in section 1182(a). The list of communicable diseases of public health significance as defined in HHS regulations is, however, limited, and does not generally include quarantinable diseases, including pandemic influenza, listed in Executive Order 13295.

Aliens with pandemic influenza could be excluded pursuant to 8 U.S.C. § 1182(f), which provides that “[w]henver the President finds that the entry of any aliens or of any class of aliens into the United States would be detrimental to the interests of the United States, he may by proclamation, and for such period as he shall deem necessary, suspend the entry of all aliens or any class of aliens as immigrants or nonimmigrants, or impose on the entry of aliens any restrictions he may deem to be appropriate.” The President may not delegate the authority to issue such a proclamation. Accordingly, if the President determined that the entry of any aliens or class of aliens was detrimental to the interests of the United States, for reasons that may include the threatened spread of a pandemic into the United States, he may issue a proclamation suspending such entry and directing enforcement by all Federal agencies.

**Control of Communicable Diseases.** The Public Health Service Act (PHSA), 42 U.S.C. § 264, authorizes the Secretary of Health and Human Services to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States, or from one State or possession into any other State or possession. Under section 362 of the PHSA, 42 U.S.C. § 265, the Secretary of Health and Human Services may prohibit, in whole or in part, the introduction of persons and property from such countries or places as he/she shall designate for the purpose of averting a serious danger of the introduction of a communicable disease into the United States if he determines that such a prohibition is in the interest of the public health.

**Vessels en route to the United States.** Section 366 of the PHSA (42 U.S.C. § 269) requires vessels at foreign ports clearing or departing for the United States to obtain a bill of health from a U.S. consular officer, U.S. Public Health Service officer, or other U.S. medical officer, unless otherwise prescribed in regulations. Historically, a bill of health was a document required from ships in international traffic that set forth the sanitary history and condition of the vessel and, in some cases, the condition of the port during the time of departure. Foreign quarantine regulations in part 71 currently state that a bill of health is not required. Under the CDC’s proposed rule, the CDC Director, to the extent permitted by law and in consultation with such other Federal agencies as the Director may deem necessary, would be authorized to require a foreign carrier clearing or departing for a U.S. port to obtain a bill of health from a U.S. consular officer or a medical officer designated for such purpose.

*Animals, Poultry, and Wildlife*

**The Animal Health Protection Act (AHPA) of 2002**, 7 U.S.C. 8301 et seq. The AHPA, described in detail

in Authorities Chapter 7, gives the Secretary of Agriculture a broad range of authorities to use in the event of an outbreak of avian influenza in the United States and to prevent the introduction of such a disease into the United States.

**The Poultry Products Inspection Act**, 21 U.S.C. 451 et seq. This Act requires the inspection of poultry products and provides for criminal penalties for adulteration and misbranding of poultry products.

**Importation of wild bird species parts and products.** The importation of these items must comply with conservation laws and treaties enforced by the Department of the Interior (DOI), including the Wild Bird Conservation Act, the Migratory Bird Treaty Act of 1918, 16 U.S.C. 703-712, the Endangered Species Act of 1973 (ESA), 16 U.S.C. 1531-1544, which implements the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), T.I.A.S. 8249; the Lacey Act Amendments of 1981, 16 U.S.C. 3371-3378; and the Bald Eagle Protection Act of 1940, 16 U.S.C. 668-668d. The DOI has the authority to take measures to restrict trade in wild birds based on threats to wildlife populations. In the event of an outbreak of highly pathogenic avian influenza (HPAI) in domestic or wild exotic birds in the United States, DOI has the authority (under 50 C.F.R. Part 13) to suspend the issuance of export and re-export permits under CITES and the ESA if such action is deemed necessary after coordination with USDA.

## Chapter 6 - Protecting Human Health

**The Public Health Service Act (PHSA)**, 42 U.S.C. §§ 201 et seq. (1994). The Secretary of Health and Human Services is authorized to develop and take such action as may be necessary to implement a plan under which the personnel, equipment, medical supplies, and other resources of the Department may be effectively used to control epidemics of any disease or condition and to meet other health emergencies and problems, (see 42 U.S.C. § 243). During an emergency proclaimed by the President, the President has broad authority to direct the services of the Public Health Service, (42 U.S.C. § 217). Under that section, the President is authorized to “utilize the [Public Health] Service to such extent and in such manner as shall in his judgment promote the public interest.”

- **Research.** Section 301 of the PHSA, 42 U.S.C. § 241, authorizes the Secretary to conduct and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental impairments of man. The Secretary is also authorized to collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities.
- **Public Health Emergency.** Section 319(a) of the PHSA, 42 U.S.C. 247d, authorizes the Secretary of Health and Human Services to declare a public health emergency and “take such action as may be appropriate to respond” to that emergency consistent with his authorities. Appropriate action may include making grants, entering into contracts, and conducting and supporting investigation into the cause, treatment, or prevention of the disease or disorder that presents the emergency. The Secretary’s declaration also can be the first step in authorizing emergency use of unapproved products or approved products for unapproved uses under section 564 of the Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3), or waiving certain regulatory requirements of the Department, such as select agents requirements, or -- when the President also declares an emergency -- waiving certain Medicare, Medicaid, and State Children’s Health Insurance Program (CHIP) provisions.

- **Vaccines and therapeutics.** The PHSA provides additional authorities for core activities of HHS that will be needed to plan and implement an emergency response. For example, sections 301, 319F-1, 402, and 405 of the PHSA authorize the Secretary of Health and Human Services to conduct and support research and development of vaccines and therapeutics. Section 351 of the PHSA and provisions of the Federal Food, Drug, and Cosmetics Act authorize the Secretary and the Food and Drug Administration (FDA) to regulate vaccine development and production. Infrastructure support for preventive health services such as immunization activities, including vaccine purchase assistance, is provided under section 317 of the PHSA.
- **Liability protection.** Section 319F-3 of the PHSA provides immunity to manufacturers, distributors, program planners, “qualified persons,” and their employees for claims for loss caused by, arising out of, relating to, or resulting from the administration or use of any “covered countermeasure” that is the subject of a declaration made by the Secretary. A covered countermeasure is a drug, device, or biological that is (1) subject to an emergency use authorization under section 564 of the Federal Food Drug and Cosmetic Act, (2) used against an epidemic or pandemic and either approved or subject to an IND, or (3) a security countermeasure as defined under the Project BioShield Act. Section 319F-4 allows the Secretary to, by declaration, establish an emergency fund in the Treasury which will be used to provide compensation for injuries directly caused by administration of a covered countermeasure.
- **Strategic National Stockpile.** Section 319F-2 of the PHSA authorizes the Secretary, in coordination with the Secretary of Homeland Security, to maintain the Strategic National Stockpile to provide for the emergency health security of the United States.
- **Quarantine.** Section 361 of the PHSA (42 U.S.C. § 264), authorizes the Secretary of Health and Human Services to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States, or from one State or possession into any other State or possession. Implementing regulations are found at 42 C.F.R. Parts 70 and 71. The HHS Centers for Disease Control and Prevention (CDC) administers these regulations as they relate to quarantine of humans. Diseases for which individuals may be quarantined are specified by Executive Order; the most recent change to the list of quarantinable diseases was Executive Order 13375 of April 1, 2005, which amended Executive Order 13295 by adding “influenza caused by novel or re-emergent influenza viruses that are causing, or have the potential to cause, a pandemic” to the list. CDC issued a new proposed rule updating these regulations on November 30, 2005. 70 Fed. Reg. 71892 ([www.cdc.gov/ncidod/dq/nprm/index.htm](http://www.cdc.gov/ncidod/dq/nprm/index.htm)). Other provisions in Title III of the PHSA permit HHS to establish quarantine stations, provide care and treatment for persons under quarantine, and provide for quarantine enforcement by specified components of DHS and cooperating State and local entities.
- **Vaccine Development.** Further, HHS has broad authority to coordinate vaccine development, distribution, and use activities under section 2102 of the PHSA, describing the functions of the National Vaccine Program. The Secretary has authority for health information and promotion activities under title XVII and other sections of the PHSA. HHS can provide support to States and localities for emergency health planning under title III of the PHSA.
- **National Goals.** Under section 1701 of the PHSA, 42 U.S.C. § 300u, the Secretary is authorized to formulate national goals for health information, promotion, health services, and education

and to undertake activities, including training, support, planning, and technical assistance, to carry out those goals.

- **Mobilizing the Commissioned Corps.** Section 203 of the PHSA, 42 U.S.C. § 204, authorizes the Federal Government to mobilize officers of the United States Public Health Service Regular Commissioned Corps and the Reserve Commissioned Corps, including commissioned corps officers who are veterinarians, in times of emergencies.

**Department of Veterans Affairs (VA) Authorities.** The primary function of the Veterans Health Administration (VHA) is to provide a complete medical and hospital service for the medical care and treatment of veterans. Section 8111A of title 38 of the U.S. Code authorizes the Secretary to provide care to members of the Armed Forces during a time of war or national emergency. Section 1784 of title 38 authorizes the Secretary to furnish hospital care or medical services as a humanitarian service to non-VA beneficiaries in emergency cases. Section 1785 of title 38 authorizes the Secretary to provide hospital care and medical services to non-VA beneficiaries responding to, involved in, or otherwise affected by a disaster or emergency. This provision codifies VA's existing obligations under the Federal Response Plan (now National Response Plan). These include VA's obligations under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. § 5121, et seq., and during activation of the National Disaster Medical System (NDMS), 42 U.S.C. § 300hh-11.

- The explicit language in section 8111A and the legislative history of section 1785 indicate that during declared major disasters and emergencies and activation of NDMS, the highest priority for receiving VA care and services goes to service-connected veterans, followed by members of the Armed Forces receiving care under section 8111A and then by individuals affected by a disaster or emergency described in section 1785 (i.e., individuals requiring care during a declared disaster or emergency, or during activation of the NDMS). As a practical matter, when faced with individuals who require emergency medical treatment (e.g., during a disaster or emergency situation), VHA practitioners must prioritize based on medical need. This may require deferring routine or elective care for veterans in order to treat medical emergencies. Life-threatening conditions are treated prior to less severe or routine conditions, regardless of priority. Such prioritization is not dictated by statute or regulation. Rather, it is derived from the general authority granted to the Secretary (and through delegation to the Under Secretary for Health and to health care providers) to provide "needed care" to veterans. Thus, during a disaster or an emergency, VA has flexibility and discretion in providing needed care.

**Exemption of Certain International Persons from Quarantine or other Restrictions.** There are certain legal bases pursuant to which Federal authorities could insist that certain people on an aircraft be released from quarantine (e.g., diplomats and their families are "inviolable" under the Vienna Convention on Diplomatic Relations; United Nations (UN) diplomats are "inviolable" under the UN General Convention on Privileges and Immunities and the HQ Agreement; diplomats attending UN conferences are "inviolable" under the General Convention; consular officers (not families) are potentially "inviolable" under Articles 40 and 41 of the Vienna Convention on Consular Relations; and heads of States are generally subject to immunity).

**ENHANCE 911 Act of 2004.** Pub. L. No. 108-494. This Act requires officials of the Department of Transportation and the Department of Commerce to establish a joint program to facilitate coordination and communication between Federal, State, and local communications systems, emergency personnel, public safety organizations, telecommunications carriers, and telecommunications equipment manufac-



turers and vendors. The Act also requires those agencies to create an E-911 Implementation Coordination Office to implement that program. The Office will be housed at the Department of Transportation, National Highway Traffic Safety Administration (NHTSA) and is required to: develop, collect, and disseminate information concerning practices, procedures, and technology used in the implementation of E-911 services.

### Other Authorities

**The Defense Production Act**, 50 U.S.C. p. §§ 2601-2171 (2002). Under the DPA, agencies can: (1) issue rated orders to manufacturers to give Government orders priority over all other orders, (2) issue rated orders to non-influenza countermeasure manufacturing facilities to manufacture influenza vaccine or antiviral medications, or (3) pursuant to DHS/FEMA regulations, and in consultation with Department of Justice (DOJ) and the Federal Trade Commission, convene industry and execute voluntary agreements as to how industry might meet the Government's vaccine and antiviral requirements.

## Chapter 7 - Protecting Animal Health

**The Animal Health Protection Act (AHPA) of 2002**, 7 U.S.C. 8301 et seq. The AHPA enables the Secretary of Agriculture to prevent, detect, control, and eradicate diseases and pests of animals, such as avian influenza, in order to protect animal health, the health and welfare of people, economic interests of livestock and related industries, the environment, and interstate and foreign commerce in animals and other articles. The AHPA provides a broad range of authorities to use in the event of an outbreak of avian influenza in the United States and to prevent the introduction of such a disease into the United States. The Secretary is specifically authorized to carry out operations and measures to detect, control, or eradicate any pest or disease of livestock, which includes poultry, 7 U.S.C. 8308, and to promulgate regulations and issue orders to carry out the AHPA (see 7 U.S.C. 8315). The Secretary may also prohibit or restrict the importation, entry, or interstate movement of any animal, article, or means of conveyance to prevent the introduction into or dissemination within the United States of any pest or disease of livestock (7 U.S.C. 8303 8305). Section 421 of the Homeland Security Act, 6 U.S.C. 231, transferred to the Secretary of Homeland Security certain agricultural import and entry inspection functions under the AHPA, including the authority to enforce the prohibitions or restrictions imposed by USDA. Under certain specified circumstances, the Secretary of Agriculture may declare an extraordinary emergency to regulate intrastate activities or commerce (7 U.S.C. 8306). The Secretary also has authority to cooperate with other Federal agencies, States, or political subdivisions of States, national or local governments of foreign countries, domestic or international organizations or associations, Indian tribes, and other persons to prevent, detect, control, or eradicate avian influenza (7 U.S.C. 8310).

**The Poultry Products Inspection Act (PPIA) of 1957**, 21 U.S.C. 452. The PPIA provides for the inspection of poultry and poultry products and otherwise regulates the processing and distribution of such articles to prevent the movement or sale in interstate or foreign commerce of, or the burdening of such commerce by, poultry products which are adulterated or misbranded. It is essential in the public interest that the health and welfare of consumers be protected by assuring that poultry products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. Unwholesome, adulterated, or misbranded poultry products impair the effective regulation of poultry products in interstate or foreign commerce, are injurious to the public welfare, destroy markets for wholesome, not adulterated, and properly labeled and packaged poultry products, and result in sundry losses to poultry producers and processors of poultry and poultry products, as well as injury to consumers. All articles and poultry which are regulated under the PPIA are either in interstate or foreign commerce or substantially affect

such commerce, and that regulation by the Secretary of Agriculture and cooperation by the States and other jurisdictions are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers. USDA statutory authorities to inspect and condemn animal carcasses and parts that may become adulterated or otherwise unfit may be relied upon for government action in appropriate situations.

**The Virus-Serum-Toxin Act**, 21 U.S.C. 151 et seq. The Secretary of Agriculture is authorized under this act to regulate veterinary biological products. These products generally act through a specific immune process and are intended for use in the treatment, including prevention, diagnosis, or cure, of diseases in animals. They include, but are not limited to, vaccines, bacterins, sera, antisera, antitoxins, toxoids, allergens, diagnostic antigens prepared from, derived from, or prepared with microorganisms, animal tissues, animal fluids, or other substances of natural or synthetic origin.

**Public Health Security and Bioterrorism Preparedness and Response Act of 2002**, Pub. L. 107-188, 116 Stat. 594 (2002). Title II of this act, “Enhancing Controls on Dangerous Biological Agents and Toxins” (sections 201-231), provides for the regulation of certain biological agents and toxins by HHS (subtitle A, sections 201-204) and USDA (subtitle B, sections 211-213, also known as the Agricultural Bioterrorism Protection Act of 2002). The Act also provides for interagency coordination between the two departments regarding certain agents and toxins that present a threat to both human and animal health. The regulations governing HHS’s select agent program are found at part 73 of title 42 of the CFR; the regulations governing USDA’s select agent program are found at part 331 of title 7 of the CFR (plants) and part 121 of title 9 of the CFR (animals). For HHS, the CDC is designated as the agency with primary responsibility for the select agent program. The Animal and Plant Health Inspection Service (APHIS) is the USDA agency fulfilling that role for the provisions applicable to animals and plants. These statutes and their implementing regulations require entities, such as private, State, and Federal research laboratories, universities, and vaccine companies, that possess, use, or transfer biological agents or toxins which are determined to pose a severe threat to public health and safety, to animal or plant health, or to animal or plant products register these agents with APHIS or CDC. USDA’s select agent regulations may be applicable in the event of an outbreak of avian influenza, as HPAI is listed as select agent under USDA regulations. For example, the USDA regulations will govern the possession, use, or movement of an HPAI virus in connection with any research attendant to a response to the outbreak. At the same time, it should be noted that the Agricultural Bioterrorism Protection Act provides that the Secretary may grant exemptions from the applicability of provisions of the regulations, in the case of listed agents or toxins, if the Secretary determines that such exemptions are consistent with protecting animal and plant health, and animal and plant products.

**Animal Damage Control Act of 1931**, 46 Stat. 1468, codified as amended at 7 U.S.C. §§ 426-426b (2000), and the **Rural Development, Agriculture, and Related Agencies Appropriations Act of 1988**, Pub. L. No. 100-202, 101 Stat. 1329-133 (codified at 7 U.S.C. § 426c (2000)). Under these acts, USDA has authority to cooperate with other Federal agencies, States, local jurisdictions, individuals, public and private agencies, organizations, and institutions while conducting a program involving animal species that are injurious and/or a nuisance to, among other things, agriculture, horticulture, forestry, animal husbandry, wildlife, and human health and safety, as well as conducting a program involving mammal and bird species that are reservoirs for zoonotic diseases.

**The Fish and Wildlife Act (FWA) of 1956**, 16 U.S.C. § 742a et seq. The FWA establishes a comprehensive national fish and wildlife policy and authorizes the Secretary of the Interior to take steps required for the development, management, conservation, and protection of fish and wildlife resources through research,



land acquisition, facilities development, and other means. The FWA authorizes the Secretary to direct a program of continuing research, extension, and information services on fish and wildlife matters, both domestically and internationally.

**The Migratory Bird Treaty Act (MBTA) of 1918**, 16 U.S.C. §§ 703-712. The MBTA places with the Secretary of the Interior Federal responsibility for protection and management of migratory birds and implements four international treaties that affect migratory birds common to the United States, Canada, Mexico, Japan, and the former Soviet Union. The MBTA makes it unlawful to hunt, kill, capture, possess, or otherwise take migratory birds, including their feathers, other parts, nests, or eggs, except as allowed by the Secretary through permit or regulation.

**The Fish and Wildlife Coordination Act of 1934**, 16 U.S.C. 661-667e. This act authorizes the Secretary of the Interior to provide assistance to, and cooperate with, Federal, State, and public or private agencies and organizations in the conservation of wildlife and in controlling losses of wildlife from disease and other causes. It also authorizes the Secretary to make surveys and investigations of wildlife of the public domain, including lands and waters or interests therein acquired or controlled by any agency of the United States.

**Commissioned Corps.** Section 203 of the PHSA, 42 U.S.C. § 204, authorizes the Federal Government to mobilize officers of the United States Public Health Service Regular Commissioned Corps and the Reserve Commissioned Corps, including commissioned corps officers who are veterinarians, in times of emergencies. Under section 361 of the PHSA, 42 U.S.C. § 264, HHS may make and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into States or possessions or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Secretary may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures as in his judgment may be necessary.

## Chapter 8 - Law Enforcement, Public Safety, and Security

**Protecting Federal Facilities and Property.** DHS is charged with protecting the buildings, grounds, and property that are owned, occupied, or secured by the Federal Government (including any agency, instrumentality, or wholly-owned or mixed-ownership corporation thereof) and the persons on the property (40 U.S.C. 1315). DHS may designate employees of the Department of Homeland Security, including employees transferred to the Department from the Office of the Federal Protective Service of the General Services Administration pursuant to the Homeland Security Act of 2002, as officers and agents for duty in connection with the protection of property owned or occupied by the Federal Government and persons on the property, including duty in areas outside the property to the extent necessary to protect the property and persons on the property. While engaged in the performance of official duties, an officer or agent designated under this section may enforce Federal laws and regulations for the protection of persons and property, and carry out such other activities for the promotion of homeland security as the Secretary may prescribe.

**Strategic National Stockpile.** In accordance with Public Law 108-276 (Project BioShield Act of 2004) and Emergency Support Function #8 - Public Health and Medical Services (ESF #8), DHS will coordinate with HHS and DOJ in ensuring the adequate physical security of the stockpile. ESF #8 instructs DOJ to provide stockpile security and quarantine enforcement upon request of HHS.

## Assistance to States in Maintaining Order

**Emergency Federal Law Enforcement Assistance Act.** Upon written request by a Governor, the Attorney General can coordinate and deploy emergency Federal law enforcement assistance to State and local law enforcement authorities (42 U.S.C. § 10501). Federal law enforcement agencies that are authorized to provide assistance to State and local government officials by enforcing State and local law should be duly deputized to do so under State and local statutes.

**Robert T. Stafford Disaster Relief and Emergency Assistance Act.** In disaster and emergency situations, this Act authorizes Federal agencies to assist in the provision of State and local public health measures, including by providing logistical or materials support to State and local law enforcement (42 U.S.C. §§ 5170, 5192-5193, 5195a). The Act also authorizes DHS/FEMA to “*procure by condemnation or otherwise, construct, lease, transport, store, maintain, renovate, or distribute materials and facilities for emergency preparedness*,” (emphasis added). The term “materials” includes “raw materials, supplies, medicines, equipment, component parts, and technical information and processes necessary for emergency preparedness,” (*id.* § 5195a(5)); the term “facilities” includes “buildings, shelters, utilities, and land,” (*id.* § 5195(a)(6)). The term “emergency preparedness” includes measures to be undertaken in preparation for anticipated hazards, during a hazard, or following a hazard. An influenza pandemic would fit within the broad definition of “hazard” (see, *id.* § 5195a(a)(1), 5195a(a)(3)).

**The Insurrection Act,** 10 U.S.C. §§ 331-335. The President may, upon request of a State legislature, or the Governor when the legislature cannot be convened, send the Armed Forces as necessary to suppress an insurrection against State authority (*id.* at § 331). Ordinarily requests under this provision specify that the violence cannot be brought under control by State and local law enforcement agencies and the State National Guard troops. In addition, the President may use the Armed Forces or the federalized National Guard as he considers it necessary to suppress any insurrection, domestic violence, unlawful combination, or conspiracy if it (1) so hinders the execution of State and Federal law that people are deprived of their rights secured by the Constitution and laws, or (2) opposes or obstructs the execution of Federal law (*id.* at § 333). The President may also use the Armed Forces of the federalized National Guard to enforce Federal law (*id.* at § 332). This statutory authority is an exception to the Posse Comitatus Act, 18 U.S.C. § 1385 (2002), authorizing the military to make arrests, conduct searches, and perform other traditional law enforcement functions.

Under the Insurrection Act, the President may use the National Guard (when called into Federal service), reserves (when called to active duty), and members of the Armed Forces to enforce Federal laws or to suppress the insurrection. DOD has an established protocol, the Commander, U.S. Joint Forces Command Civil Disturbance Plan (“Garden Plot”). Under this plan, the Attorney General is responsible for receiving and coordinating requests for military assistance. The military on-scene commander acts in coordination with the Senior Civilian Representative of the Attorney General, most likely the U.S. Attorney in the given area.

**Military Support for Civilian Law Enforcement Agencies.** The Secretary of Defense may, in accordance with other applicable law, make available any equipment (including associated supplies or spare parts), base facility, or research facility of the DOD to any Federal, State, or local civilian law enforcement official for law enforcement purposes (10 U.S.C. § 372(a)). Training and personnel to maintain and operate equipment may also be provided (10 U.S.C. §§ 373-4).

*Enforcement of Quarantines*

**State and local Quarantines.** State and local officials draw their authority to enforce State and local quarantines from State and local law. Under section 311 of the PHSA, 42 U.S.C. § 243(a), the Secretary of Health and Human Services is authorized to accept State and local authorities' assistance in the enforcement of Federal quarantine rules and regulations, and is required to assist State and local authorities in the enforcement of their quarantines and other health regulations.

The U.S. Coast Guard, and "military officers commanding in any fort or station upon the seacoast," as well as Customs officers, which may include Customs and Border Protection officers and Immigration and Customs Enforcement special agents, must, at the direction of the Secretary of Health and Human Services, aid in the execution of such State quarantines and other health laws "according to their respective powers and within their respective precincts" (42 U.S.C. § 97).

The President also could use the Insurrection Act (see above) and use the Armed Forces or federalized National Guard to help suppress violence arising out of a State quarantine, as for any other law enforcement activity permitted under the Insurrection Act, 10 U.S.C. §§ 331-335, provided the requirements for using the Act described above are met (e.g., if the President is asked by a State to assist and if the defiance to the State quarantine orders amounts to an insurrection against State authority that the State cannot handle (see 10 U.S.C. § 331), or there is widespread unlawful activity that has the effect of depriving people of rights secured by the Constitution and laws) (see 10 U.S.C. § 333).

**Federal Quarantines.** Customs officers, which may include Customs and Border Protection officers and Immigration and Customs Enforcement special agents, and the U.S. Coast Guard have specific authority and responsibility to assist with the enforcement of quarantines at ports of entry (42 U.S.C. § 268). With regard to other Federal law enforcement officers, the United States Marshals Service has the broadest of Federal law enforcement missions, 28 U.S.C. § 565; and, along with other Department of Justice agencies (FBI, DEA, ATF) can be directed by the Attorney General to enforce quarantines. The U.S. Marshals Service can also deputize other Federal law enforcement officers throughout the executive branch to give them law enforcement powers in circumstances that extend beyond those for which they are otherwise statutorily authorized to exercise them, as was done during Hurricane Katrina.

Under the Insurrection Act the President may direct the military to enforce quarantines, or conduct security functions such as guarding stockpiles and pharmaceuticals, when he finds it necessary to enforce Federal law (see 10 U.S.C. §§ 332-334), or other prerequisites for use of the Act described above are met.

**Criminal Sanctions.** The violation of Federal quarantine regulations is a crime punishable by a fine of not more \$1,000 or by imprisonment for not more than 1 year, or both (42 U.S.C. § 271). Additionally, individuals may be fined up to \$250,000 if a violation of the regulation results in death, or up to \$100,000 if a violation of the regulation does not result in death (18 U.S.C. §§ 3559, 3571(c)).

## **Chapter 9 - Institutions: Protecting Personnel and Ensuring Continuity of Operations**

**The Occupational Safety and Health Act of 1970** authorizes the Secretary of Labor to promote the safety and health of America's workers by setting and enforcing standards; providing training, outreach, and education; and establishing partnerships. The Occupational Safety and Health Administration has promulgated several standards to protect workers that would be particularly important in the event of a pandemic influenza outbreak. These standards include, but are not limited to: 29 CFR 1910.120 (Hazardous Waste Operations and Emergency Response), 29 CFR 1910.132 (Personal Protective Equipment), 29 CFR 1910.134 (Respiratory Protection), and 29 CFR 1910.1030 (Bloodborne Pathogens).



# Exhibit L

# HHS Pandemic Influenza Plan



U.S. Department  
of Health and  
Human Services

November 2005







# **HHS Pandemic Influenza Plan**

U.S. Department  
of Health and  
Human Services

**November 2005**





# HHS Pandemic Influenza Plan

## TABLE OF CONTENTS

|                                                                                                                  |            |
|------------------------------------------------------------------------------------------------------------------|------------|
| Statement by Secretary Leavitt .....                                                                             | 1          |
| Preface .....                                                                                                    | 2          |
| Executive Summary .....                                                                                          | 4          |
| <b>PART 1 – STRATEGIC PLAN .....</b>                                                                             | <b>15</b>  |
| The Pandemic Influenza Threat .....                                                                              | 16         |
| Planning Assumptions .....                                                                                       | 18         |
| Doctrine for a Pandemic Influenza Response .....                                                                 | 20         |
| Key Pandemic Influenza Response Actions and Key Capabilities for Effective Implementation .....                  | 22         |
| Roles and Responsibilities of HHS Agencies and Offices .....                                                     | 26         |
| HHS Actions for Pandemic Influenza Preparedness and Response .....                                               | 32         |
| Appendices .....                                                                                                 |            |
| A. National Response Plan .....                                                                                  | A-1        |
| B. Pandemic Influenza Background .....                                                                           | B-3        |
| C. WHO Pandemic Phases .....                                                                                     | C-8        |
| D. NVAC/ACIP Recommendations on Use of Vaccines and NVAC Recommendations<br>on Pandemic Antiviral Drug Use ..... | D-10       |
| E. Legal Authorities .....                                                                                       | E-30       |
| F. Current Key HHS Activities .....                                                                              | F-33       |
| G. HHS Research Activities .....                                                                                 | G-42       |
| H. International Partnership on Avian and Pandemic Influenza .....                                               | H-59       |
| I. Acronym List .....                                                                                            | I-61       |
| J. Internet Resources on Pandemic Influenza .....                                                                | J-63       |
| <b>PART 2 – PUBLIC HEALTH GUIDANCE FOR STATE AND LOCAL PARTNERS .....</b>                                        | <b>I-1</b> |
| Introduction .....                                                                                               | I-1        |
| Supplement 1: Pandemic Influenza Surveillance .....                                                              | S1-1       |
| Supplement 2: Laboratory Diagnostics .....                                                                       | S2-1       |
| Supplement 3: Healthcare Planning .....                                                                          | S3-1       |
| Supplement 4: Infection Control .....                                                                            | S4-1       |
| Supplement 5: Clinical Guidelines .....                                                                          | S5-1       |
| Supplement 6: Vaccine Distribution and Use .....                                                                 | S6-1       |
| Supplement 7: Antiviral Drug Distribution and Use .....                                                          | S7-1       |
| Supplement 8: Community Disease Control and Prevention .....                                                     | S8-1       |
| Supplement 9: Managing Travel-Related Risk of Disease Transmission .....                                         | S9-1       |
| Supplement 10: Public Health Communications .....                                                                | S10-1      |
| Supplement 11: Workforce Support: Psychosocial Considerations and<br>Information Needs .....                     | S11-1      |





# Statement by Health and Human Services Secretary Mike Leavitt:

One of the most important public health issues our Nation and the world faces is the threat of a global disease outbreak called a pandemic. No one in the world today is fully prepared for a pandemic -- but we are better prepared today than we were yesterday - and we will be better prepared tomorrow than we are today.

This *HHS Pandemic Influenza Plan* provides a blueprint from which to prepare for the challenges that lie ahead of us. Being prepared and responding effectively involves everyone: individuals, communities, businesses, States, Federal agencies, international countries and organizations. Here at home, we can use this *Plan* to create a seamless preparedness network where we are all working together for the benefit of the American people.

In the century past, we have experienced influenza pandemics three times: as recently as 1968 and 1957 and what has been called the Great Influenza in 1918, a pandemic that killed 40-50 million people worldwide. At some point in our nation's future another virus will emerge with the potential to create a global disease outbreak. History teaches us that everything we do today to prepare for that eventuality will have many lasting benefits for the future. We will realize important advances in healthcare, and we will be better prepared for other types of emergencies.

I am humbled by the enormity of the challenge that the global community confronts should there be a pandemic. Public cooperation and global partnerships will be essential tools in fighting back and creating a constant state of readiness. If together we take the steps necessary, we will be able to save the lives of millions of people in our country and all around the world.

Mike Leavitt  
Health and Human Services Secretary



# preface

Adequate planning for a pandemic requires the involvement of every level of our nation, and indeed, the world. The ubiquitous nature of an influenza pandemic compels federal, state and local governments, communities, corporations, families and individuals to learn about, prepare for, and collaborate in efforts to slow, respond to, mitigate, and recover from a potential pandemic. The development, refinement, and exercise of pandemic influenza plans by all stakeholders are critical components of preparedness.

This document, the **HHS Pandemic Influenza Plan**, serves as a blueprint for all HHS pandemic influenza preparedness planning and response activities. This plan updates the August 2004 draft HHS Pandemic Influenza Preparedness and Response Plan and features important additions and refinements. The Plan integrates changes made in the 2005 World Health Organization (WHO) classification of pandemic phases and expansion of international guidance and now is consistent with the National Response Plan (NRP) published in December 2004.

The **HHS Pandemic Influenza Plan** has three parts, the first two of which are contained in this document. Part 1, the **Strategic Plan** outlines federal plans and preparation for public health and medical support in the event of a pandemic. It identifies key roles of HHS and its agencies in a pandemic and provides planning assumptions for federal, state and local governments and public health operations plans. Part 2, **Public Health Guidance for State and Local Partners**, provides detailed guidance to state and local health departments in 11 key areas. Parts 1 and 2 will be regularly updated and refined. These documents will serve as tools for continued engagement with stakeholders, state and local partners.

Part 3, which is currently under development, will consist of **HHS Agencies' Operational Plans**. Each HHS component will prepare, maintain, update and exercise an operational plan that itemizes their specific roles and responsibilities in the event of a pandemic. These individual plans will also include detailed continuity of operations plans such as strategies for ensuring that critical everyday functions of each operating division are identified and maintained in the presence of the expected decreased staffing levels of a pandemic event. In addition to operations, these plans will elaborate on coordination, command and control, logistics, and planning, as well as financial and administration considerations.

Recognizing that an influenza pandemic has the capacity to cause disruptions across all levels of governments and in all communities, pandemic influenza preparedness is a shared responsibility. The following list includes some of the additional plans that will be required to mitigate the impact of a pandemic and to ensure continuity of essential services:

*All plans should remain living documents. They should be updated periodically in the time before, during, and after a pandemic. All plans should be exercised to identify weaknesses and promote effective implementation.*



#### ■ International and Global Planning

Every nation should develop comprehensive strategies and contingency plans for a global pandemic. These plans should be coordinated regionally and at the global level. The opportunity to contain an initial outbreak can only be realized in the presence of a sophisticated global strategy.

#### ■ National Strategy for Pandemic Influenza

The National Strategy provides a framework for future U.S. Government planning efforts. It acknowledges that the Nation must have a system of plans at all levels of government and in all sectors outside of government, that can be integrated to address the pandemic threat.

#### ■ State and Local Pandemic Influenza Plans

These plans should detail how health departments and other agencies of state and local governments and tribal nations will prevent, mitigate, respond and recover from an influenza pandemic. They should be community specific where appropriate and should contemplate specific local and community needs.

#### ■ Corporate, Infrastructure and Critical Service Provider Plans

School systems, hospitals, healthcare providers, community infrastructure providers and employers should develop plans that identify how they will respond in the event of an influenza pandemic.

All plans should remain living documents. They should be updated periodically in the time before, during, and after a pandemic. All plans should be exercised to identify weaknesses and promote effective implementation. Pandemic influenza response can be optimized by effectively engaging stakeholders during all phases of pandemic planning and response.



*Although the timing, nature and severity of the next pandemic cannot be predicted with any certainty, preparedness planning is imperative to lessen the impact of a pandemic.*



## executive summary

An influenza pandemic has the potential to cause more death and illness than any other public health threat. If a pandemic influenza virus with similar virulence to the 1918 strain emerged today, in the absence of intervention, it is estimated that 1.9 million Americans could die and almost 10 million could be hospitalized over the course of the pandemic, which may evolve over a year or more. Although the timing, nature and severity of the next pandemic cannot be predicted with any certainty, preparedness planning is imperative to lessen the impact of a pandemic. The unique characteristics and events of a pandemic will strain local, state, and federal resources. It is unlikely that there will be sufficient personnel, equipment, and supplies to respond adequately to multiple areas of the country for a sustained period of time. Therefore, minimizing social and economic disruption will require a coordinated response. Governments, communities, and other public and private sector stakeholders will need to anticipate and prepare for a pandemic by defining roles and responsibilities and developing continuity of operations plans.

This document, the **HHS Pandemic Influenza Plan**, serves as a blueprint for all HHS pandemic influenza preparedness and response planning. Part 1, the **Strategic Plan**, describes a coordinated public health and medical care strategy to prepare for, and begin responding to, an influenza pandemic. Part 2, **Public Health Guidance for State and Local Partners** provides guidance on specific aspects of pandemic influenza planning and response for the development of state and local preparedness plans.

### Part 1 – Strategic Plan

Part 1 describes the pandemic influenza threat and outlines planning assumptions and doctrine for the HHS pandemic influenza response. In addition, it identifies key pandemic response actions and the necessary capabilities for effective implementation. Finally, the **Strategic Plan** assigns lead roles and responsibilities for response actions to specific HHS agencies and offices.

#### The Pandemic Influenza Threat

A pandemic occurs when a novel influenza virus emerges that can infect and be efficiently transmitted among individuals because of a lack of pre-existing immunity in the population. The extent and severity of a pandemic depends on the specific characteristics of the virus.

Although a novel influenza virus could emerge from anywhere in the world at any time, scientists are particularly concerned about the avian influenza (H5N1) currently circulating in Asia and parts of Europe.



Outbreaks of influenza H5N1 have occurred among poultry in several countries in Asia since 1997. The H5N1 avian influenza virus is widespread in the region and has become endemic in migratory birds and several other animal species. As of October 2005, cases of human H5N1 infection have been reported in Thailand, Vietnam, Cambodia, and Indonesia. The reported death rate for these cases has been about 50 percent, although the true number of people who have been exposed to and infected by the H5N1 virus is unknown. While most of the reported cases seem to have occurred from direct contact with infected poultry or contaminated surfaces, the source of infection has not been documented in every instance. Of additional concern are the few instances where secondary transmission from person to person may have occurred. Given these events, we are currently in a Pandemic Alert Phase 3, defined by WHO as "human infections with a new subtype but no human-to-human spread or at most rare instances of spread to a close contact."<sup>1</sup>

### **Pandemic Planning Assumptions**

As a result of the widespread emergence and spread of the H5N1 virus among birds, public health experts and government officials are escalating and intensifying their pandemic preparedness planning. Uncertainty about the magnitude of the next pandemic mandates planning for a severe pandemic such as occurred in 1918. Characteristics of an influenza pandemic that must be considered in strategic planning include:

- The ability of the virus to spread rapidly worldwide;
- The fact that people may be asymptomatic while infectious;
- Simultaneous or near-simultaneous outbreaks in communities across the U.S., thereby limiting the ability of any jurisdiction to provide support and assistance to other areas;
- Enormous demands on the healthcare system;
- Delays and shortages in the availability of vaccines and antiviral drugs; and
- Potential disruption of national and community infrastructures including transportation, commerce, utilities and public safety due to widespread illness and death among workers and their families and concern about on-going exposure to the virus.

<sup>1</sup> [http://www.who.int/csr/resources/publications/influenza/who\\_dcs\\_gd991.pdf](http://www.who.int/csr/resources/publications/influenza/who_dcs_gd991.pdf)



### Doctrine for HHS Pandemic Influenza Planning and Response

The ongoing outbreaks of avian influenza in Asia and the progression from the interpandemic period (the period prior to human infections) to a pandemic alert (once human infections have occurred) have prompted HHS to enhance its preparedness planning and activities. In addition to the characteristics of a pandemic noted above, HHS' preparedness planning and response activities are guided by the following principles:

1. Preparedness will require coordination among federal, state and local government and partners in the private sector.
2. An informed and responsive public is essential to minimizing the health effects of a pandemic and the resulting consequences to society.
3. Domestic vaccine production capacity sufficient to provide vaccine for the entire U.S. population is critical, as is development of vaccine against each circulating influenza virus with pandemic potential and acquisition of sufficient quantities to help protect first responders and other critical personnel at the onset of a pandemic.
4. Quantities of antiviral drugs sufficient to treat 25% of the U.S. population should be stockpiled.
5. Sustained human-to-human transmission anywhere in the world will be the triggering event to initiate a pandemic response by the United States.
6. When possible and appropriate, protective public health measures will be employed to attempt to reduce person-to-person viral transmission and prevent or delay influenza outbreaks.
7. At the onset of a pandemic, vaccine, which will initially be in short supply, will be procured by HHS and distributed to state and local health departments for immunization of pre-determined priority groups.
8. At the onset of a pandemic, antiviral drugs from public stockpiles will be distributed to health care providers for administration to pre-determined priority groups.

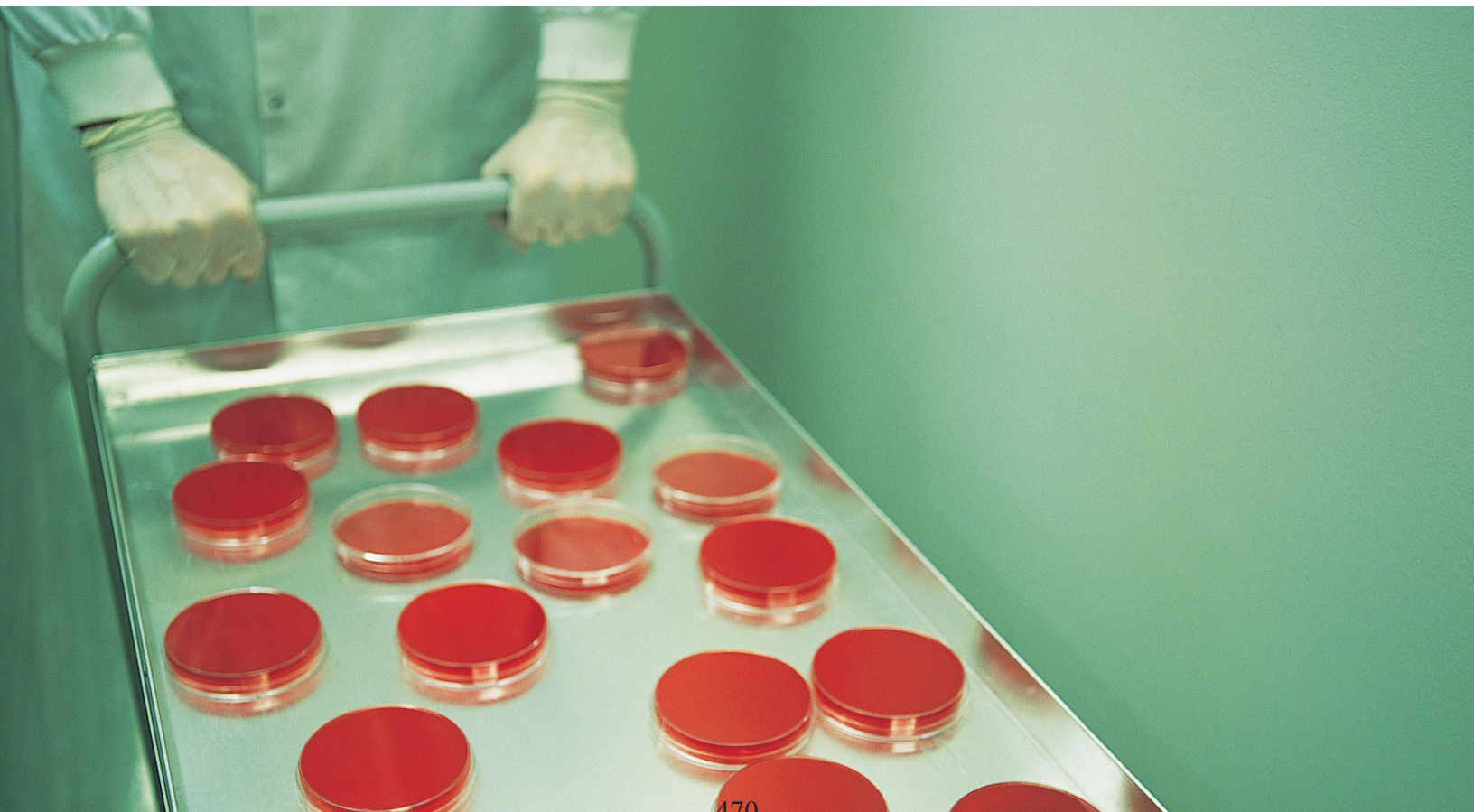
*Sustained human-to-human transmission anywhere in the world will be the triggering event to initiate a pandemic response by the United States.*

### Key Pandemic Response Elements and Capabilities for Effective Implementation

The nature of the HHS response will be guided by the epidemiologic features of the virus and the course of the pandemic. An influenza pandemic will place extraordinary and sustained demands not only on public health and health care providers, but also on providers of essential services across the United States and around the globe. Realizing that pandemic influenza preparedness is a process, not an isolated event, to most effectively implement key pandemic response actions, specific capabilities must be developed through preparedness activities implemented before the pandemic occurs. This plan outlines key actions for an effective pandemic response, involving surveillance, investigation, protective public health measures; vaccines and antiviral drug production; healthcare and emergency response; and communications and public outreach. In addition, the **Strategic Plan** sorts these actions by the WHO Pandemic phases. Recognizing that this potential public health catastrophe can occur at any time, HHS has aggressively embarked on preparing for a pandemic.

### Surveillance, Investigation, Protective Public Health Measures

Aggressive surveillance measures ensure early detection and isolation of novel virus strains. Since a new virus could emerge anywhere in the world, surveillance activities must be conducted globally. To date, working with our international partners, HHS has greatly intensified its U.S. and global surveillance activities. In addition, HHS is developing comprehensive infection control strategies.







Once sustained human infection is documented, early in a pandemic, especially before a vaccine is available or during a period of limited supply, HHS may implement travel-related and community-based public health strategies in order to impede the spread of the virus and reduce the number of people infected. In particular, travel advisories and precautions, screening of persons arriving from affected areas, closing schools, restricting public gatherings, quarantine of exposed persons and isolation of infected persons may be implemented with the intent of slowing introduction and transmission of the virus. The use and continuation of these interventions will be determined by assessments of their effectiveness.

#### **Vaccines and Antiviral Drugs**

Vaccines and antiviral drugs have the potential to significantly reduce morbidity and mortality during a pandemic. In addition, vaccines and antiviral drugs may also limit viral spread. Although antiviral drugs can be stockpiled, a pandemic vaccine can only be made once the pandemic virus is identified. HHS is currently initiating vaccine development and clinical testing leading toward a vaccine that may provide complete or partial protection against potential pandemic viral strains and also increasing and diversifying antiviral medicines in the Strategic National Stockpile (SNS), a cache of medical and pharmaceutical supplies maintained by HHS. FDA is currently working with industry to facilitate the development, licensure/approval, production and availability of pandemic influenza countermeasures.

At the onset of a pandemic, HHS will accelerate its ongoing work with industry to facilitate the production and distribution of antiviral drugs and pandemic vaccines. HHS will continue to monitor antiviral drug and pandemic vaccine distribution effectiveness, and adverse events. Since vaccine and antiviral drugs are likely to be in short supply at the onset of an influenza pandemic, identification of predefined groups in which these medications will be used will be discussed as part of federal planning activities. HHS will work with state and local governments to develop guidelines and operational plans for the distribution of available supplies of a pandemic vaccine and antiviral drugs.

### Healthcare and Emergency Response

An effective healthcare and emergency response requires planning and coordination among all levels of government and providers of direct patient care and essential services. HHS is working with its state and local partners to increase health care surge capacity of medical equipment, materials and personnel.

During a pandemic, HHS will work with states and local governments, and the private sector to optimize healthcare and emergency response. Since a pandemic may unfold in an unpredictable way, HHS actions in a pandemic will be shaped by regular assessments and adjustments of its strategies.

### Communications and Public Outreach

Dissemination of information to all Americans is a critical component of effective pandemic planning and response. HHS is currently developing communication and outreach materials and messages. In addition, HHS is developing strategies to address psychosocial concerns and procedures for implementation of communications plans for health care providers and the public.

During a pandemic, HHS will provide honest, accurate and timely information on the pandemic to the public. It will also monitor and evaluate its interventions and will communicate lessons learned to healthcare providers and public health agencies on the effectiveness of clinical and public health responses.

*All state, local, and tribal governments must be prepared to detect the earliest cases of pandemic influenza infection and disease, to minimize illness and morbidity, and to decrease social disruption and economic loss.*

## Part 2 – Public Health Guidance to State and Local Partners

All state, local, and tribal governments must be prepared to detect the earliest cases of pandemic influenza infection and disease, to minimize illness and morbidity, and to decrease social disruption and economic loss. Specific guidance and recommendations for pandemic influenza preparedness for state, local and tribal governments are detailed in eleven supplements in Part 2.



- **Surveillance (Supplement 1)** provides recommendations to state and local partners on surveillance for influenza viruses and disease to monitor the health impact of influenza throughout the pandemic phases.
- **Laboratory Diagnostics (Supplement 2)** provides recommendations to state and local public health partners and other laboratories on the use of diagnostic tests to detect, characterize, and monitor novel subtypes of influenza, including avian influenza A (H5N1) and other viruses with pandemic potential.
- **Healthcare Planning (Supplement 3)** provides healthcare partners with recommendations for developing plans to respond to an influenza pandemic with a focus on planning for pandemic influenza surveillance, decision-making structures for responding to a pandemic, hospital communications, education and training, patient triage, clinical evaluation and admission, facility access, occupational health, distribution of vaccines and antiviral drugs, surge capacity, and mortuary issues. Planning for the provision of care in non-hospital settings—including residential care facilities, physicians' offices, private home healthcare services, emergency medical services, federally qualified health centers, rural health clinics, and alternative care sites—is also addressed.
- **Infection Control (Supplement 4)** provides guidance to healthcare and public health partners on basic principles of infection control for limiting the spread of pandemic influenza including the selection and use of personal protective equipment; hand hygiene and safe work practices; cleaning and disinfection of environmental surfaces; handling of laboratory specimens; and post-mortem care. The guidance also covers infection control practices related to the management of infectious patients, the protection of persons at high-risk for severe influenza or its complications, and issues concerning occupational health.
- **Clinical Guidelines (Supplement 5)** provides clinical procedures for the initial screening, assessment, and management of patients with suspected novel influenza during the Interpandemic and Pandemic Alert Periods and for patients with suspected pandemic influenza during the Pandemic Period.



*Robust preparedness for the next pandemic requires coordination with state and local emergency responders.*

*HHS encourages all levels of government to use this plan and begin refining their own.*

- **Vaccine Distribution and Use (Supplement 6)** provides recommendations to state and local partners and other stakeholders on planning for the different elements of a pandemic vaccination program, including vaccine distribution, vaccination of priority groups, monitoring of adverse events, tracking of vaccine supply and administration, vaccine coverage and effectiveness studies, communications, legal preparedness, training, data collection on use, effectiveness, safety and the development of drug resistance.
- **Antiviral Drug Distribution and Use (Supplement 7)** provides recommendations to state and local partners on the distribution and use of antiviral drugs for treatment and prophylaxis throughout the pandemic phases, including issues such as procurement, distribution to pre-defined priority groups, legal preparedness, training and data collection.
- **Community Disease Control and Prevention (Supplement 8)** provides recommendations to state and local partners on the use of disease containment strategies to prevent or decrease transmission during different pandemic phases.
- **Managing Travel-Related Risks of Disease (Supplement 9)** provides recommendations to state and local partners on travel-related containment strategies that can be used during different phases of an influenza pandemic, including strategies that range from distribution of travel health alert notices, to isolation and quarantine of new arrivals, to restriction or cancellation of nonessential travel.
- **Public Health Communications (Supplement 10)** outlines key influenza pandemic risk communications concepts including:
  - When health risks are uncertain, as likely will be the case during an influenza pandemic, people need information about what is known and unknown, as well as interim guidance to formulate decisions to help protect their health and the health of others;
  - An influenza pandemic will generate immediate, intense, and sustained demand for information from the public, healthcare providers, policy makers, and news media;
  - Timely and transparent dissemination of clear, accurate, science-based, culturally competent information about pandemic influenza and the progress of the response can build public trust and confidence;
  - Coordination of message development and release of information among federal, state, and local health officials is critical to help avoid confusion that can undermine public trust, raise fear and anxiety, and impede response measures;
  - Information to public audiences should be technically correct and sufficiently complete to encourage support of policies and official actions.
- **Workforce Support: Psychosocial Considerations and Information Needs (Supplement 11)** focuses on the institutionalization of psychosocial support services that will help workers manage emotional stress during the response to an influenza pandemic and resolve related personal, professional, and family issues.

Robust preparedness for the next pandemic also requires coordination with state and local emergency responders. HHS encourages all levels of government to use this plan and begin refining their own. To this end, HHS plans to engage all stakeholders in an ongoing dialogue to refine and better coordinate preparedness plans.



# part 1

---

## Strategic Plan







# strategic plan

## TABLE OF CONTENTS

|                                                                                                                 |      |
|-----------------------------------------------------------------------------------------------------------------|------|
| The Pandemic Influenza Threat .....                                                                             | 14   |
| Planning Assumptions.....                                                                                       | 16   |
| Doctrine for a Pandemic Influenza Response.....                                                                 | 18   |
| Key Pandemic Influenza Response Actions and Key                                                                 |      |
| Capabilities for Effective Implementation .....                                                                 | 20   |
| Roles and Responsibilities of hhs Agencies and Offices.....                                                     | 24   |
| hhs Actions for Pandemic Influenza Preparedness and Response .....                                              | 30   |
| <b>Appendices</b>                                                                                               |      |
| A. National Response Plan .....                                                                                 | A-1  |
| B. Pandemic Influenza Background.....                                                                           | B-3  |
| C. WHO Pandemic Phases .....                                                                                    | C-8  |
| D. NVAC/ACIP Recommendations on Use of Vaccines and NVAC Recommendations<br>on Pandemic Antiviral Drug Use..... | D-10 |
| E. Legal Authorities.....                                                                                       | E-30 |
| F. Current Key HHS Activities.....                                                                              | F-33 |
| G. HHS Research Activities.....                                                                                 | G-42 |
| H. International Partnership on Avian and Pandemic Influenza.....                                               | H-59 |
| I. Acronym List .....                                                                                           | I-61 |
| J. Internet Resources on Pandemic Influenza.....                                                                | J-63 |



# the pandemic influenza threat

Influenza A viruses have infected many different animals including ducks, chickens, pigs, whales, horses, and seals. Influenza A viruses normally seen in one species can sometimes cross over and cause illness in another species. This creates the possibility that a new virus will develop, either through mutation or mixing of individual viruses, in turn creating the possibility for new viral strains that can be highly infective, readily transmissible, and highly lethal in humans. When a pandemic virus strain emerges, 25% to 35% of the population could develop clinical disease, and a substantial fraction of these individuals could die. The direct and indirect health costs alone (not including disruptions in trade and other costs to business and industry) have been estimated to approach \$181 billion for a moderate pandemic (similar to those in 1957 and 1968) with no interventions. Faced with such a threat, the U.S. and its international partners will need to respond quickly and forcefully to reduce the scope and magnitude of the potentially catastrophic consequences.

Such a threat currently exists in the form of the H5N1 virus, which is spreading widely and rapidly in domestic and migratory fowl across Asia and Europe. As of October 2005, this strain has infected more than 115 humans, killing approximately 50% of those known to be infected. The virus is now endemic in many bird species so that elimination of the virus is not feasible. If this virus mutates in such a way that it becomes capable of spreading efficiently from person to person, the feared pandemic could become a reality. (Additional background information is provided in Appendix B.)





*When a pandemic virus strain emerges, 25% to 35% of the population could develop clinical disease, and a substantial fraction of these individuals could die.*

Emergence of a human influenza virus with pandemic potential presents a formidable response challenge. If such a strain emerged in one or a few isolated communities abroad or within the U.S. and was detected quickly, containment of the outbreak(s), though very difficult, might be feasible, thereby preventing or significantly retarding the spread of disease to other communities. Containment attempts would require stringent infection-control measures such as bans on large public gatherings, isolation of symptomatic individuals, prophylaxis of the entire community with antiviral drugs, and various forms of movement restrictions—possibly even including a quarantine.

The resources required for such vigorous containment would almost certainly exceed those available in the affected community(ies). Thus, if a containment attempt is to have a chance of succeeding, the response must employ the assets of multiple partners in a well coordinated way. For isolated outbreaks outside the U.S., this means effective multinational cooperation in executing containment protocols designed and exercised well in advance. For isolated outbreaks within the U.S., this would require effective integration of the response assets of local, state, and federal governments and those of the private sector.

The National Response Plan (NRP), based on the principles of incident management, provides an appropriate conceptual and operational framework for a multi-party response to an outbreak of a potential influenza pandemic in one or a few U.S. communities. In particular, the NRP is designed to engage the response assets of multiple public and private partners and bring them to bear in a coordinated way at one or a few incident sites. (Appendix A provides additional information regarding the NRP.)

If efforts to contain isolated outbreaks within the U.S. were unsuccessful and influenza spread quickly to affect many more communities either simultaneously or in quick succession—the hallmark of a pandemic—response assets at all levels of government and the private sector would be taxed severely. Communities would need to direct all their influenza response assets to their own needs and would have little to spare for the needs of others. Moreover, as the number of affected communities grows, their collective need would spread the response assets of states and the federal government ever thinner. In the extreme, until a vaccine against the pandemic virus would become available in sufficient quantity to have a significant impact on protecting public health, thousands of communities could be countering influenza simultaneously with little or no assistance from adjacent communities, the state, or the federal government. Preparedness planning for pandemic influenza response must take this prospect into account.



# planning assumptions

Pandemic preparedness planning is based on assumptions regarding the evolution and impacts of a pandemic. Defining the potential magnitude of a pandemic is difficult because of the large differences in severity for the three 20th-century pandemics. While the 1918 pandemic resulted in an estimated 500,000 deaths in the U.S., the 1968 pandemic caused an estimated 34,000 U.S. deaths. This difference is largely related to the severity of infections and the virulence of the influenza viruses that caused the pandemics. The 20th century pandemics have also shared similar characteristics. In each pandemic, about 30% of the U.S. population developed illness, with about half seeking medical care. Children have tended to have the highest rates of illness, though not of severe disease and death. Geographical spread in each pandemic was rapid and virtually all communities experienced outbreaks.

Pandemic planning is based on the following assumptions about pandemic disease:

- Susceptibility to the pandemic influenza subtype will be universal.
- The clinical disease attack rate will be 30% in the overall population. Illness rates will be highest among school-aged children (about 40%) and decline with age. Among working adults, an average of 20% will become ill during a community outbreak.
- Of those who become ill with influenza, 50% will seek outpatient medical care.
- The number of hospitalizations and deaths will depend on the virulence of the pandemic virus. Estimates differ about 10-fold between more and less severe scenarios. Because the virulence of the influenza virus that causes the next pandemic cannot be predicted, two scenarios are presented based on extrapolation of past pandemic experience (Table 1).

**Table 1. Number of Episodes of Illness, Healthcare Utilization, and Death Associated with Moderate and Severe Pandemic Influenza Scenarios\***

| Characteristic          | Moderate (1958/68-like) | Severe (1918-like) |
|-------------------------|-------------------------|--------------------|
| Illness                 | 90 million (30%)        | 90 million (30%)   |
| Outpatient medical care | 45 million (50%)        | 45 million (50%)   |
| Hospitalization         | 865,000                 | 9,900,000          |
| ICU care                | 128,750                 | 1,485,000          |
| Mechanical ventilation  | 64,875                  | 742,500            |
| Deaths                  | 209,000                 | 1,903,000          |

\*Estimates based on extrapolation from past pandemics in the United States. Note that these estimates do not include the potential impact of interventions not available during the 20th century pandemics.

*Risk groups for severe and fatal infections cannot be predicted with certainty.*

- Risk groups for severe and fatal infections cannot be predicted with certainty. During annual fall and winter influenza season, infants and the elderly, persons with chronic illnesses, and pregnant women are usually at higher risk of complications from influenza infections. In contrast, in the 1918 pandemic, most deaths occurred among young, previously healthy adults.
- The typical incubation period (the time between acquiring the infection until becoming ill), for influenza averages 2 days. We assume this would be the same for a novel strain that is transmitted between people by respiratory secretions.
- Persons who become ill may shed virus and can transmit infection for one-half to one day before the onset of illness. Viral shedding and the risk for transmission will be greatest during the first 2 days of illness. Children will shed the greatest amount of virus and, therefore are likely to pose the greatest risk for transmission.
- On average about 2 secondary infections will occur as a result of transmission from someone who is ill. Some estimates from past pandemics have been higher, with up to about 3 secondary infections per primary case.
- In an affected community, a pandemic outbreak will last about 6 to 8 weeks. At least two pandemic disease waves are likely. Following the pandemic, the new viral subtype is likely to continue circulating and to contribute to seasonal influenza.
- The seasonality of a pandemic cannot be predicted with certainty. The largest waves in the U.S. during 20th century pandemics occurred in the fall and winter. Experience from the 1957 pandemic may be instructive in that the first U.S. cases occurred in June but no community outbreaks occurred until August and the first wave of illness peaked in October.

*In an affected community, a pandemic outbreak will last about 6 to 8 weeks.  
At least two pandemic disease waves are likely.*



# doctrine for a pandemic

HHS will be guided by the following principles in initiating and directing its response activities:

- 1) In advance of an influenza pandemic, HHS will work with federal, state, and local government partners and the private sector to coordinate pandemic influenza preparedness activities and to achieve interoperable response capabilities.<sup>2</sup>
- 2) In advance of an influenza pandemic, HHS will encourage all Americans to be active partners in preparing their states, local communities, workplaces, and homes for pandemic influenza and will emphasize that a pandemic will require Americans to make difficult choices. An informed and responsive public is essential to minimizing the health effects of a pandemic and the resulting consequences to society.
- 3) In advance of an influenza pandemic, HHS, in concert with federal partners, will work with the pharmaceutical industry to develop domestic vaccine production capacity sufficient to provide vaccine for the entire U.S. population as soon as possible after the onset of a pandemic and, during the pre-pandemic period, to produce up to 20 million courses of vaccine against each circulating influenza virus with pandemic potential and to expand seasonal influenza domestic vaccine production to cover all Americans for whom vaccine is recommended through normal commercial transactions.
- 4) In advance of an influenza pandemic, HHS, in concert with federal partners and in collaboration with the States, will procure sufficient quantities of antiviral drugs to treat 25% of the U.S. population and, in so doing, stimulate development of expanded domestic production capacity sufficient to accommodate subsequent needs through normal commercial transactions. HHS will stockpile antiviral medications in the Strategic National Stockpile, and states will create and maintain local stockpiles.
- 5) Sustained human-to-human transmission anywhere in the world will be the triggering event to initiate a pandemic response by the United States. Because we live in a global community, a human outbreak anywhere means risk everywhere.
- 6) The US will attempt to prevent an influenza pandemic or delay its emergence by striving to arrest isolated outbreaks of a novel influenza wherever circumstances suggest that such an attempt might be successful, acting in concert with WHO and other nations as appropriate. At the core of this strategy will be basic public health measures to reduce person-to-person transmission.

<sup>2</sup> Throughout this document, the term "state and local" is inclusive of municipal, county, territorial, and tribal governments and health authorities.

*In advance of an influenza pandemic, HHS will encourage all Americans to be active partners in preparing their states, local communities, workplaces, and homes for pandemic influenza and will emphasize that a pandemic will require Americans to make difficult choices.*



- 7) At the onset of an influenza pandemic, HHS, in concert with federal partners, will work with the pharmaceutical industry to procure vaccine directed against the pandemic strain and to distribute vaccine to state and local public health departments for pre-determined priority groups based on pre-approved state plans.
- 8) At the onset of an influenza pandemic, HHS, in collaboration with the states, will begin to distribute and deliver antiviral drugs from public stockpiles to healthcare facilities and others with direct patient care responsibility for administration to pre-determined priority groups.





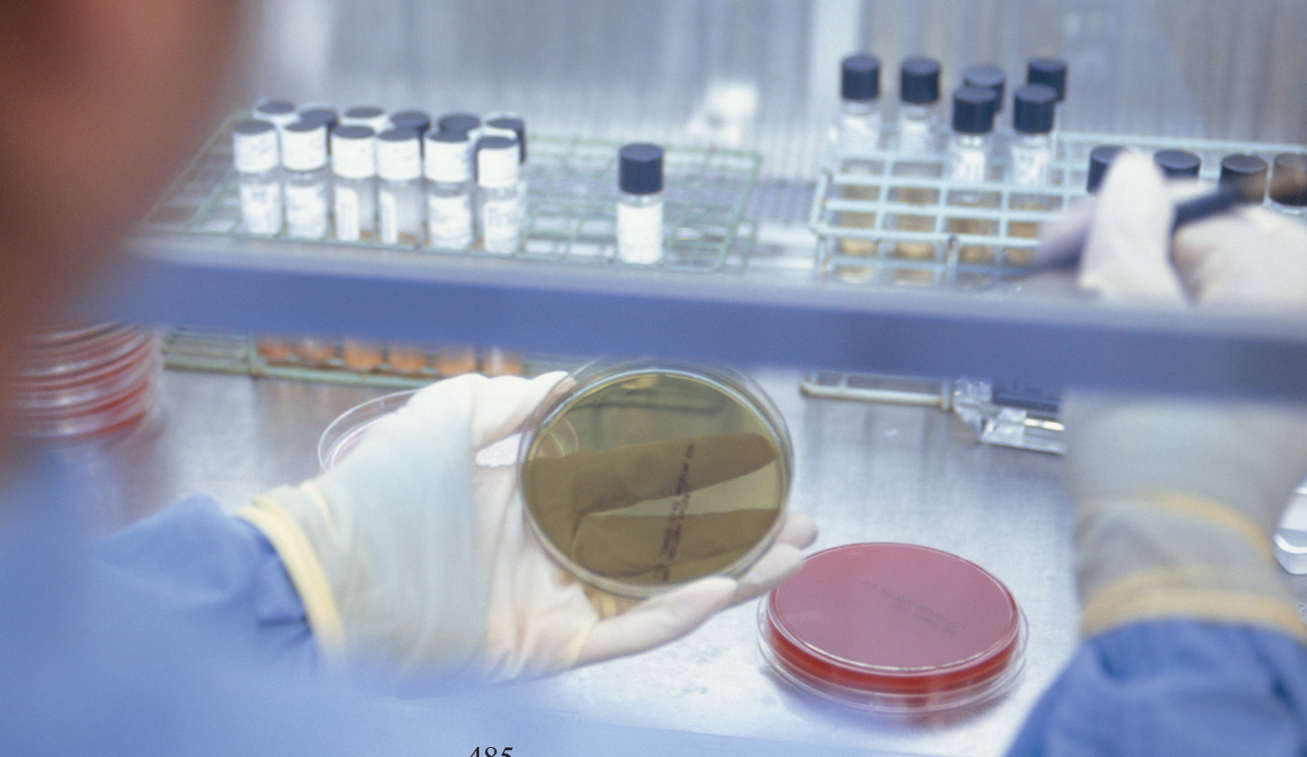


# key pandemic influenza response

An influenza pandemic will place extraordinary and sustained demands on public health and healthcare systems and on providers of essential community services across the U.S. and throughout the world. The nature and scope of these demands will vary over the course of the pandemic. Table 2 lists key pandemic response actions that public health, medical, and other government authorities at all levels must be prepared to take to mitigate the potentially catastrophic consequences of a pandemic. A more detailed list of HHS-specific response actions categorized by WHO pandemic phase is shown in Tables 4 through 9.

Pandemic influenza preparedness is a process, not an isolated event. To most effectively implement key pandemic response actions, specific capabilities must be developed through preparedness activities implemented before the pandemic occurs. For each key pandemic response activity, Table 2 summarizes capabilities needed for implementation of an effective response.

*An influenza pandemic will place extraordinary and sustained demands on public health and healthcare systems and on providers of essential community services across the U.S. and throughout the world.*



**Table 2. Key Pandemic Response Elements and Key Capabilities for their Effective Implementation**

| Key Pandemic Response Actions                                                                                                                                                                                                                                                                                                       | Key Capabilities Needed for Implementation of an Effective Response                                                                                                                                                                                                                                                                                  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Surveillance, Investigation, and Protective Public Health Measures</b>                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                      |
| 1. Increase international surveillance and collaborate in outbreak investigation to track the emerging epidemiological patterns and impacts of disease caused by the novel influenza virus subtype.                                                                                                                                 | 1. Agreements with international partners, including international organizations, and other U.S. government agencies, to improve the capability and capacity of local public health systems in countries where a potential pandemic virus strain is likely to emerge so that accurate and timely influenza surveillance information can be obtained. |
| 2. Determine feasibility of containing the initial outbreak of a potential pandemic, working in consultation with international partners, and if feasible, implement containment activities.                                                                                                                                        | 2. Assets (people, facilities, equipment, supplies, and exercised procedures), deployed at home and abroad, to investigate, and if feasible, mount an immediate emergency response.                                                                                                                                                                  |
| 3. Obtain samples of the potential pandemic virus from infected people and distribute them to laboratories for genetic, antigenic, and antiviral resistance analysis. Prepare reference strains for distribution to vaccine manufacturers. Assess cross-protection of stockpiled vaccine, if available, against the pandemic virus. | 3. Laboratory assets to characterize the novel influenza virus strain (genetic and antigenic characteristics and antiviral resistance) and rapidly develop a vaccine reference strain for distribution to manufacturers. Agreements with international partners to quickly obtain samples.                                                           |
| 4. Implement surveillance and control measures (e.g., isolation of cases, quarantine of contacts, antiviral drug treatment and prophylaxis) at points-of-entry to decrease introduction and spread of the pandemic virus in the U.S.                                                                                                | 4. Quarantine stations and related protections at all major U.S. ports of entry to limit the introduction of pandemic influenza, isolate cases, and trace contacts.                                                                                                                                                                                  |
| 5. Enhance domestic surveillance to detect pandemic outbreaks, track the spread of virus in near real-time, and assess impacts on health and infrastructure.                                                                                                                                                                        | 5. Real-time or near real-time electronic connectivity with major domestic healthcare institutions and public health departments across the U.S. to obtain daily influenza disease and resource availability information.<br><br>Widely available, reliable, rapid, sensitive, and accurate diagnostic tests.                                        |
| 6. Implement public health measures to limit the spread of infection (e.g., canceling public gatherings) as well as individual measures to decrease the risk of acquiring or spreading infection (e.g., personal hygiene, isolation of ill persons).                                                                                | 6. Assets (people, facilities, equipment, supplies, and exercised procedures) to effect wide-spread individual and community-based infection control measures and educate individuals on personal protection strategies.                                                                                                                             |
| 7. Monitor pandemic response actions and assess their effectiveness.                                                                                                                                                                                                                                                                | 7. Assets (people, facilities, equipment, supplies, and exercised procedures) to analyze data continually during the course of the pandemic to guide response activities and to assess the safety and efficacy of interventions.                                                                                                                     |



Table 2. (Continued)

| Key Pandemic Response Actions                                                                                                                                                                                                                                                                          | Key Capabilities Needed for Implementation of an Effective Response                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Vaccines and Antiviral Drugs</b>                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <p>1. Consider administration of pre-pandemic stockpiled vaccine, if available, to pre-defined groups critical to the pandemic response. This could provide partial immune protection and/or prime the immune system for a protective response once a targeted pandemic vaccine becomes available.</p> | <p>1. A national stockpile of 40 million doses (2 doses per person) of vaccine against influenza virus subtypes considered to pose a substantial pandemic risk (currently avian H5N1).</p>                                                                                                                                                                                                                                                                                                                                              |
| <p>2. In conjunction with other parties, manufacture, test, license, and produce vaccine against the specific pandemic virus strain.</p>                                                                                                                                                               | <p>2. Domestic influenza vaccine manufacturing capacity to produce sufficient pandemic vaccine for the U.S. population within 6 months of the onset of an influenza pandemic.</p> <p>Consider liability concerns vaccine manufacturers.</p> <p>A library of reference strains and reagents for novel influenza subtypes; clinical trials of candidate pandemic influenza vaccines in the U.S. and affected areas.</p>                                                                                                                   |
| <p>3. Allocate and administer pandemic vaccine to pre-defined priority groups. Ensure security for protection of scarce vaccines.</p>                                                                                                                                                                  | <p>3. State and local vaccine distribution plans, guided by recommendations for use of pandemic vaccine when supply is short, that are specific, implementable, and which have been practiced in tabletop and field exercises.</p>                                                                                                                                                                                                                                                                                                      |
| <p>4. Monitor vaccine coverage and track vaccine use so persons who receive initial pandemic vaccine can return for a second dose, if required. Monitor for adverse events following vaccination and conduct studies to assess vaccine safety and effectiveness.</p>                                   | <p>4. Assets (people, facilities, equipment, supplies, and exercised procedures) to monitor vaccine coverage, adverse events, and effectiveness.</p>                                                                                                                                                                                                                                                                                                                                                                                    |
| <p>5. Allocate stockpiled antiviral drugs for use in pre-defined high-risk and critical infrastructure populations.</p>                                                                                                                                                                                | <p>5. Availability of at least 81 million treatment courses of approved antiviral drugs—enough for treatment of approximately 25% of the U.S. population and 6 million additional treatment courses in reserve for domestic containment.</p> <p>State and local antiviral drug distribution plans, guided by recommendations for use of pandemic vaccine when supply is short, that are specific, implementable, and have been practiced in tabletop and field exercises.</p> <p>Increased U.S.-based antiviral drug manufacturing.</p> |

Table 2. (Continued)

| Key Pandemic Response Actions                                                                                                                                                                                                                                   | Key Capabilities Needed for Implementation of an Effective Response                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Vaccines and Antiviral Drugs (Continued)</b>                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 6. Monitor antiviral drug distribution and adverse events, and conduct studies to further assess safety and effectiveness.                                                                                                                                      | 6. Assets (people, facilities, equipment, supplies, and exercised procedures) to monitor antiviral distribution, adverse events, and effectiveness.                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Healthcare and Emergency Response</b>                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 1. Distribute stockpiled ventilators and other medical material needed to treat and care for infected individuals to health departments and federal agencies that provide direct patient care.                                                                  | 1. Equipment and supplies maintained in the Strategic National Stockpile and state stockpiles sufficient to enhance medical surge capacity.                                                                                                                                                                                                                                                                                                                                                                                         |
| 2. Deploy Federal Medical Stations, as available, to provide healthcare surge capacity in hardest hit areas.                                                                                                                                                    | 2. Federal Medical Stations and healthcare assets (people, facilities, equipment, supplies, and exercised procedures) to enhance medical surge capacity.                                                                                                                                                                                                                                                                                                                                                                            |
| 3. Test patient specimens using highly accurate (sensitive and specific) rapid diagnostic tests to identify pandemic outbreaks in communities and contribute to management decisions.                                                                           | 3. Widely available accurate rapid diagnostic methods to detect and characterize influenza viruses.                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 4. Assist communities with surge mortuary services to accommodate a large number of expected fatalities.                                                                                                                                                        | 4. Assets (people, facilities, equipment, supplies, and exercised procedures) for the timely, safe, and respectful disposition of the deceased.                                                                                                                                                                                                                                                                                                                                                                                     |
| 5. Provide psychosocial support to responders and affected communities.                                                                                                                                                                                         | 5. Institutionalization of psychosocial support services and development of workforce resiliency programs.                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Communications and Outreach</b>                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 1. Public education and information campaign to 1) communicate measures the public can implement to minimize risk and decrease the spread of infection; 2) provide honest, accurate, understandable and timely information; and 3) counter confusion and panic. | <p>1. Pre-tested risk communication materials that provide the public easy-to-understand information regarding pandemic influenza and how individuals can protect themselves and help others during an influenza pandemic, and appropriate use of vaccines and antiviral drugs.</p> <p>Pre-tested procedures through which public authorities within each community will provide information and guidance to the public (including marginalized, disadvantaged, and foreign-language populations) during an influenza pandemic.</p> |



# roles and responsibilities of HHS agencies and offices

Table 3 provides a summary of the roles and responsibilities assigned to select HHS officials, agencies, and divisions.



**Table 3. Summary of Major Pandemic Response Roles of HHS Officials, Agencies, and Divisions**

| <b>HHS Official, Agency, or Division</b>                              | <b>Roles</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Secretary of Health and Human Services                                | <ul style="list-style-type: none"> <li>■ Directs all HHS pandemic response activities</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Assistant Secretary for Public Health Emergency Preparedness (ASPHEP) | <ul style="list-style-type: none"> <li>■ Coordinates HHS pandemic response activities</li> <li>■ Monitors effectiveness of response activities and modifies strategies, as needed</li> <li>■ Coordinates and communicates with other federal departments and agencies</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Assistant Secretary for Health (ASH)                                  | <ul style="list-style-type: none"> <li>■ Directs the Office of the Surgeon General in deployment of U.S. Public Health Service Commissioned Corps assets</li> <li>■ Directs Regional Health Administrators who will be members of Secretary's Emergency Response Teams (SERTs) in their regions</li> <li>■ Advises Secretary on Public Health and Science as he directs HHS pandemic response activities</li> <li>■ Coordinates operations planning efforts of HHS agencies, operational divisions and offices</li> <li>■ Assists with public communications and coordination with state and local public health partners</li> <li>■ Directs the National Vaccine Program Office (NVPO) in pandemic preparedness and response</li> </ul> |
| Director of Office of Intergovernmental Affairs                       | <ul style="list-style-type: none"> <li>■ Advises and coordinates outreach and communications to state, local and tribal officials and national intergovernmental organizations</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Assistant Secretary for Legislation (ASL)                             | <ul style="list-style-type: none"> <li>■ Coordinates Congressional outreach and communications</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Office of the Surgeon General (OSG)                                   | <ul style="list-style-type: none"> <li>■ Deploys U.S. Public Health Service Commissioned Corps assets (upon approval of the Assistant Secretary for Health)</li> <li>■ Assists with public communication and education</li> <li>■ Assists and coordinate pandemic planning with partner federal health service providers, specifically the Indian Health Service, The Federal Bureau of Prisons and the Coast Guard</li> </ul>                                                                                                                                                                                                                                                                                                           |
| Assistant Secretary for Public Affairs (ASPA)                         | <ul style="list-style-type: none"> <li>■ Coordinates public information and communications</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| National Vaccine Program Office (NVPO)                                | <ul style="list-style-type: none"> <li>■ Chairs Secretary's Task Force on Influenza Preparedness</li> <li>■ Coordinates communication between vaccine and antiviral drug manufacturers and HHS agencies</li> <li>■ Coordinates development of after-action report and lessons learned</li> <li>■ Maintains close communication with drug and vaccine manufacturers</li> </ul>                                                                                                                                                                                                                                                                                                                                                            |

Table 3. (Continued)

| HHS Official, Agency, or Division                      | Roles                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|--------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Office of the General Counsel (OGC)                    | <ul style="list-style-type: none"> <li>■ Advises on legal issues and authorities related to key pandemic response activities</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Director of the Office of Global Health Affairs (OGHA) | <ul style="list-style-type: none"> <li>■ Coordinates interactions with health authorities in other governments and international organizations in coordination with the Department of State</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Centers for Disease Control and Prevention (CDC)       | <ul style="list-style-type: none"> <li>■ Conducts and supports clinical and virological influenza surveillance</li> <li>■ Monitors pandemic health impacts</li> <li>■ Implements travel-related and community containment measures as necessary to prevent the introduction, transmission, and spread of pandemic disease from foreign countries into the US, from state to state or in the event of inadequate local control</li> <li>■ Coordinates pandemic response activities with state, local and tribal public health agencies</li> <li>■ Investigates epidemiology and clinical characteristics of pandemic disease</li> <li>■ Assists in vaccination program implementation and in monitoring and investigating vaccine adverse events</li> <li>■ Assesses vaccine effectiveness in population-based studies</li> <li>■ Coordinates antiviral and other drug delivery from the Strategic National Stockpile</li> <li>■ Monitors antiviral drug use, effectiveness, safety, and resistance</li> <li>■ Monitors the implementation/effectiveness of protective public health measures</li> <li>■ Recommends and evaluates community measures to prevent and control disease</li> <li>■ Makes recommendations on diagnosis and management of influenza illness</li> <li>■ Makes recommendations on appropriate infection control recommendations</li> <li>■ Communicates with state and local health departments and other public health partners</li> <li>■ Communicates information on pandemic health impacts as directed by the ASPA</li> <li>■ Maintains close communication with drug and vaccine manufacturers</li> </ul> |
| Centers for Medicare and Medicaid                      | <ul style="list-style-type: none"> <li>■ Provides streamlined payment mechanisms and works with prescription drug plans and Medicare managed care plans, as necessary to ensure ready access to pandemic influenza vaccine and antiviral prescription drugs for Medicare's population</li> <li>■ Communicates specific guidance and supports pandemic flu response activities of the nation's hospitals, home health agencies, skilled nursing facilities and other health care providers, suppliers and practitioners that participate in Medicare and Medicaid</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

Table 3. (Continued)

| HHS Official, Agency, or Division  | Roles                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                    | <ul style="list-style-type: none"> <li>■ Communicates influenza pandemic related information through existing outreach networks to Medicare beneficiary populations</li> <li>■ Supports tracking and surveillance of Medicare patients, including high-risk and vulnerable patients who have received pandemic influenza vaccine and antiviral prescription drugs, including review of Medicare claims and quality data</li> <li>■ Supplies “real time” intelligence to other Federal health care agencies on the status of local, regional and national pandemic flu response provider activities through stakeholder association meetings and open door forums</li> <li>■ Prepares reference strains appropriate for vaccine manufacturing</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Food and Drug Administration (FDA) | <ul style="list-style-type: none"> <li>■ Regulates manufacturing process</li> <li>■ Evaluates and licenses pandemic vaccines</li> <li>■ Evaluates and approves antiviral drugs for influenza</li> <li>■ Facilitates the development, evaluation and clearance or approval of diagnostic tests and devices</li> <li>■ Prepares reagents to standardize potency of inactivated influenza vaccines</li> <li>■ Prepares reference strains appropriate for vaccine manufacturing</li> <li>■ Reviews antiviral drug and pandemic vaccine supply issues</li> <li>■ Evaluates and issues Emergency Use Authorizations when appropriate</li> <li>■ Monitors vaccine adverse events</li> <li>■ Monitors antiviral drug adverse events</li> <li>■ Maintains close communication with drug and vaccine manufacturers</li> <li>■ Evaluates investigational new drug applications (INDs) and investigational device exemptions (IDEs) for medical products that diagnose, treat, prevent or mitigate influenza</li> <li>■ Evaluates new manufacturing sites and processes for antiviral drugs</li> <li>■ Makes necessary changes in prescribing and patient information, including dosing, target populations, and other direction for use, for antiviral drugs and pandemic vaccines based on research and adverse events</li> <li>■ Evaluates long-term stability of stockpiled antiviral drugs for purposes of shelf life extension</li> <li>■ Monitors to protect against the distribution of counterfeit antiviral drugs and pandemic vaccines</li> </ul> |



Table 3. (Continued)

| HHS Official, Agency, or Division                                  | Roles                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|--------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| National Institutes of Health (NIH)                                | <ul style="list-style-type: none"> <li>■ Develops improved drugs against influenza</li> <li>■ Supports basic research, including structure/function studies of influenza virus proteins with the goal of identifying new therapeutic targets</li> <li>■ Develops and clinically evaluates novel influenza vaccines and vaccination strategies (e.g., adjuvants, delivery systems)</li> <li>■ Develops sensitive, specific, and rapid diagnostic tests for influenza</li> <li>■ Evaluates the immune response to infection and vaccination</li> <li>■ Determines the molecular basis of virulence in humans and animals</li> <li>■ Evaluates the molecular and/or environmental factors that influence the transmission of influenza viruses, including drug-resistant strains</li> <li>■ Studies the evolution and emergence of influenza viruses including the identification of factors that affect influenza host-range and virulence</li> <li>■ Supports virologic and serologic surveillance studies of the distribution of influenza viruses with pandemic potential in animals</li> <li>■ Maintains close communication with drug and vaccine manufacturers</li> <li>■ Prepares reference strains appropriate for vaccine manufacturing</li> </ul> |
| Agency for Healthcare Research and Quality (AHRQ)                  | <ul style="list-style-type: none"> <li>■ Communicates with and supports federal, state, and local public health partners on mass vaccination and surge capacity healthcare delivery plans</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Health Resources and Services Administration (HRSA)                | <ul style="list-style-type: none"> <li>■ Communicates with and provides technical assistance to support pandemic response activities of state primary care associations, health centers, and other community-based providers</li> <li>■ Promotes coordination with the National Hospital Bioterrorism Preparedness Program for surge capacity plans</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Substance Abuse and Mental Health Services Administration (SAMHSA) | <ul style="list-style-type: none"> <li>■ Communicates with and supports pandemic response activities of state, local, and tribal mental health and substance abuse agencies</li> <li>■ Communicates information on behavioral health issues, including stress and anxiety as a result of pandemic health impacts, as directed by the ASPA</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Administration for Children and Families (ACF)                     | <ul style="list-style-type: none"> <li>■ Communicates with and supports pandemic response activities of state, local, tribal, and nonprofit (including faith-based and community) human services organizations</li> <li>■ Communicates information on child and family well-being, including the importance and availability of vaccinations and antiviral drugs, as well as proper hygienic practices, to treat pandemic influenza and prevent its spread</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |



Table 3. (Continued)

| HHS Official, Agency, or Division | Roles                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                   | <ul style="list-style-type: none"> <li>■ Encourages the participation of human services providers (e.g., Head Start centers, child care centers, family resource centers, community action agencies, runaway and homeless youth shelters, and shelters for unaccompanied alien children) in making vaccines and antiviral drugs available to vulnerable populations</li> <li>■ Assists in medium- and long-term social adjustment of individuals, families, and communities following the pandemic</li> </ul> |
| Indian Health Service (IHS)       | <ul style="list-style-type: none"> <li>■ Communicates with and supports state, local, and tribal pandemic response activities at HHS, tribal, and urban Indian sites serving American Indian and Alaska Native populations</li> </ul>                                                                                                                                                                                                                                                                         |





# HHS actions for pandemic influenza preparedness and response

HHS will follow the WHO published guidance for national pandemic planning, which defines pandemic activities in six phases. WHO Phases 1 and 2 are the Interpandemic Period, which includes phases where no new influenza virus subtypes have been detected in humans.

The Pandemic Alert Period includes a phase when human infection with a novel influenza strain has been identified but no evidence has been found of transmission between people or at most rare instances of spread to a close contact (WHO Phase 3) and includes phases where person-to-person transmission is occurring in clusters with limited human-to-human transmission (WHO Phases 4 and 5). WHO Phase 6 is the Pandemic Period, in which there is increased and sustained transmission in the general population. (Appendix C describes the WHO pandemic phases in detail.)

Each pandemic phase is associated with a range of preparedness and response activities directed by the Secretary of Health and Human Services, after consultation with international authorities and others, as necessary. Given that an influenza pandemic may not unfold in a completely predictable way, decision-makers must regularly reassess their strategies and actions and make adjustments as necessary. This section highlights critical pandemic preparedness and response activities to be implemented by HHS.



*Given that an influenza pandemic may not unfold in a completely predictable way, decision-makers must regularly reassess their strategies and actions and make adjustments as necessary.*



**Table 4: WHO Pandemic Phases 1 and 2: HHS Actions**

| <b>WHO Phases 1 and 2: Interpandemic Phase Actions</b>             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|--------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Planning and Coordination                                          | <ul style="list-style-type: none"> <li>■ Assess preparedness status and identify actions needed to fill gaps.</li> <li>■ Coordinate with Federal, state and local, tribal, and private-sector authorities and organizations, and with media and the public.</li> <li>■ Develop and conduct tabletop and field exercises to evaluate and improve preparedness plans and response capabilities.</li> <li>■ Coordinate completion of pandemic preparedness and response plans at Federal, state local, tribal, and private-sector levels.</li> <li>■ Update HHS Pandemic Influenza Plan as needed.</li> <li>■ Consider indemnification and liability protection issues for affected entities, including pandemic vaccine manufacturers, pandemic vaccine distributors, and healthcare providers who administer pandemic vaccines.</li> </ul>                                                                                                                                                                                                                                                                                                                                          |
| Surveillance, Investigation, and Protective Public Health Measures | <ul style="list-style-type: none"> <li>■ Prepare reagents for identification of new influenza strains in animals and other strains with pandemic potential.</li> <li>■ Assist in domestic and international influenza outbreak investigations.</li> <li>■ Develop strategies to enhance domestic surveillance and collaborate with international organizations to improve global surveillance to allow earlier detection of novel influenza viruses.</li> <li>■ Enhance collaborations with international organizations and governments to facilitate surveillance and reporting and the ability to investigate disease outbreaks and implement containment measures that could prevent a pandemic.</li> <li>■ Develop guidance for outbreak control measures in healthcare settings and other institutions such as long-term care facilities.</li> <li>■ Develop strategies to prevent spread of infection to or within the U.S. from affected areas (e.g., travel advisories or precautions, assessment of travelers returning from affected areas).</li> <li>■ Assess pathogenicity, antiviral susceptibility, and other characteristics of novel influenza strains.</li> </ul> |
| Vaccines and Antiviral Drugs                                       | <ul style="list-style-type: none"> <li>■ Develop strategies to increase uptake of annual influenza vaccine.</li> <li>■ Expand U.S.-based influenza vaccine manufacturing capacity, diversifying vaccine production methods and suppliers.</li> <li>■ Ensure capacity exists to produce adequate doses of influenza vaccine year-round.</li> <li>■ Support development, evaluation, and U.S.-based production of an influenza vaccine produced in cell culture.</li> <li>■ Support development, evaluation and U.S.-based production of antiviral drugs.</li> <li>■ Develop vaccine reference strain and reagents for influenza strains with pandemic potential.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

Table 4. (Continued)

| WHO Phases 1 and 2: Interpandemic Phase Actions |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                 | <ul style="list-style-type: none"> <li>■ Obtain investigational lots of candidate vaccine for novel influenza strains and conduct clinical testing.</li> <li>■ Develop strategies for rapid administration of vaccines to priority populations and mechanisms to monitor vaccine effectiveness and safety.</li> <li>■ Support efforts to make antiviral drugs available to treat priority populations and to support containment, outbreak response, and protection of priority populations involved in pandemic response activities and maintenance of critical services and infrastructures.</li> </ul>                                                                 |
| Healthcare and Emergency Response               | <ul style="list-style-type: none"> <li>■ Assess surge capacity of medical (including inpatient, outpatient, and long-term care facilities) and emergency response systems (e.g. beds, ventilators, etc.) to meet expected needs during a pandemic.</li> <li>■ Assess surge capacity of federal medical assets (e.g. IHS, VA, DOD).</li> </ul>                                                                                                                                                                                                                                                                                                                             |
| Communications and Outreach                     | <ul style="list-style-type: none"> <li>■ Coordinate communication activities across federal departments and with state, local and international partners.</li> <li>■ Inform and educate the public about influenza.</li> <li>■ Communicate with state and local health departments.</li> <li>■ Develop educational materials for healthcare and human services providers, the media, and the public on pandemic influenza preparedness and response, including facilities, vaccine, and antiviral drugs in short supply.</li> <li>■ Develop strategies and materials to support a pandemic response and to promote public trust and decrease fear and anxiety.</li> </ul> |
| Research                                        | <ul style="list-style-type: none"> <li>■ Conduct research to develop and manufacture new influenza vaccines and antiviral drugs.</li> <li>■ Conduct research to decrease time needed to develop, evaluate, and produce pandemic vaccine.</li> <li>■ Conduct research to decrease time needed to develop, evaluate, and produce antiviral drugs.</li> <li>■ Conduct research on effective protective health measures.</li> </ul>                                                                                                                                                                                                                                           |

**Table 5: WHO Pandemic Phase 3: HHS Actions**

| <b>WHO Phase 3: Pandemic Alert Phase Actions (No person-to-person transmission)</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Planning and Coordination                                                           | <ul style="list-style-type: none"> <li>■ Assess preparedness status and identify actions needed to fill gaps.</li> <li>■ Collaborate with international partners to respond to pandemic alert.</li> <li>■ Inform government officials (including Congress and state health departments) and legislators of pandemic alert status.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Surveillance, Investigation, and Protective Public Health Measures                  | <ul style="list-style-type: none"> <li>■ Distribute reagents to state public health laboratories and WHO National Influenza Centers for detection of the new strain.</li> <li>■ Assist in international influenza outbreak investigations and characterize disease epidemiology and antigenic and genetic characteristics of the virus.</li> <li>■ Implement strategies to enhance domestic surveillance and to identify suspect cases in the U.S. in coordination with state and local health authorities.</li> <li>■ Provide guidance to implement outbreak control measures in healthcare settings and other institutions, such as long-term care facilities, as needed.</li> <li>■ Implement strategies to prevent the spread of infection to or within the U.S. from affected areas, in coordination with state and local health authorities.</li> </ul> |
| Vaccines and Antiviral Drugs                                                        | <ul style="list-style-type: none"> <li>■ Develop vaccine reference strain to the novel influenza virus and distribute to manufacturers.</li> <li>■ Develop reagents for evaluation of candidate vaccines to the novel strain.</li> <li>■ Test investigational lots of vaccine to the new strain.</li> <li>■ Develop a tracking system that will ensure that individuals obtain subsequent doses of vaccine and will report and monitor for adverse events.</li> <li>■ Develop a tracking system to report and monitor for adverse events in individuals given antiviral therapies.</li> <li>■ Assess status of available antiviral drugs and strategies for use.</li> <li>■ Evaluate antiviral susceptibilities of the novel strain.</li> </ul>                                                                                                               |
| Healthcare and Emergency Response                                                   | <ul style="list-style-type: none"> <li>■ Assess capacity of medical and emergency response systems to meet expected needs during a pandemic.</li> <li>■ Enhance surge capacity of federal medical systems.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Communications and Outreach                                                         | <ul style="list-style-type: none"> <li>■ Update state and local health departments, other stakeholders, and the media on status of pandemic.</li> <li>■ Enhance healthcare provider awareness of the potential for a pandemic and the importance of diagnosis and viral identification for persons with influenza-like illness, especially from potentially affected areas.</li> <li>■ Implement strategies and disseminate materials to support a pandemic response and to promote public trust and decrease fear and anxiety.</li> </ul>                                                                                                                                                                                                                                                                                                                    |

**Table 6: WHO Pandemic Phases 4 and 5: HHS Actions**

| <b>WHO Phases 4 and 5: Pandemic Alert Phase Actions –<br/>Limited human-to-human transmission</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|---------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Planning and<br>Coordination                                                                      | <ul style="list-style-type: none"> <li>■ Assess preparedness status and identify immediate actions needed to fill gaps.</li> <li>■ Establish coordination of response activities through the Secretary's Operations Center.</li> <li>■ Coordinate with the WHO and foreign governments.</li> <li>■ Notify government officials (including Congress and state health departments) and legislators of pandemic status.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Surveillance,<br>Investigation, and<br>Protective Public<br>Health Measures                       | <ul style="list-style-type: none"> <li>■ Assist in international containment efforts, if appropriate.</li> <li>■ Assist in international influenza outbreak investigations and characterize disease epidemiology and antigenic and genetic characteristics of the virus.</li> <li>■ Distribute reagents to state public health laboratories for detection of the novel strain.</li> <li>■ Continue enhanced national surveillance; identify suspect cases and/or introduction of a novel virus into the U.S.</li> <li>■ Provide education to travelers, including refugees being resettled in the U.S., and issue travel advisories, precautions, or restrictions if warranted by disease epidemiology; investigate illness among travelers returning from affected areas and implement isolation and quarantine, as needed.</li> </ul>                                                                                                                                                                                       |
| Vaccines and<br>Antiviral drugs                                                                   | <ul style="list-style-type: none"> <li>■ Develop vaccine reference strain (if not already done) and distribute to manufacturers.</li> <li>■ Develop and test investigational lots of vaccine to the new strain.</li> <li>■ Develop reagents for formulation and potency testing of pandemic vaccine.</li> <li>■ Contract with manufacturers to develop pilot lots of pandemic vaccine for clinical testing.</li> <li>■ Initiate rapid clinical studies of pandemic vaccine safety, immunogenicity, and schedule.</li> <li>■ Determine susceptibility of the novel influenza strain to antiviral drugs (if not already done).</li> <li>■ Assess supply, distribution, and production capacity of antiviral drug manufacturers.</li> <li>■ Contract with manufacturers for production of additional antiviral drugs.</li> <li>■ Ready process for investigational new drug (IND) or Emergency Use Authorization (EUA) applications for experimental vaccines and antiviral drugs available for use under EUA or IND.</li> </ul> |

**Table 6. (Continued)**

| <b>WHO Phases 4 and 5: Pandemic Alert Phase Actions – Limited human-to-human transmission</b> |                                                                                                                                                                                                                                                                                         |
|-----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Healthcare and Emergency Response                                                             | <ul style="list-style-type: none"> <li>■ Assess capacity of medical and emergency response systems to meet expected needs during a pandemic.</li> <li>■ Provide updated guidance, if indicated, to healthcare providers on clinical management and infection control.</li> </ul>        |
| Communications and Outreach                                                                   | <ul style="list-style-type: none"> <li>■ Update Congress; state, local, and tribal health departments; local officials, other stakeholders, and the media.</li> <li>■ Implement public education on the potential for a pandemic and the actions to be taken to reduce risk.</li> </ul> |

**Table 7: WHO Pandemic Phase 6, No U.S. Cases: HHS Actions**

| <b>WHO Phase 6: Pandemic Period Actions (no cases in the U.S.)</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Planning and Coordination                                          | <ul style="list-style-type: none"> <li>■ Update government officials (including Congress and state health departments) and legislators on pandemic status.</li> <li>■ Coordinate information sharing with other federal agencies, including DHS, Department of State, DOD, the WHO, and other countries.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Surveillance, Investigation, and Protective Public Health Measures | <ul style="list-style-type: none"> <li>■ Collaborate with international organizations to assess epidemiology of disease outbreaks and efficiency of person-to-person transmission, and to obtain parameter estimates to support real-time mathematical modeling.</li> <li>■ Implement travel advisories, precautions, or restrictions, as appropriate.</li> <li>■ Investigate illness among travelers returning from affected areas; implement isolation and quarantine, as needed.</li> <li>■ Assist states, as needed, in investigating potential cases of pandemic influenza.</li> <li>■ Continue activities to enhance detection of U.S. cases of influenza at borders, hospitals, and outpatient settings.</li> <li>■ Ensure availability of diagnostic reagents for pandemic influenza strain at state and local public health laboratories.</li> <li>■ Provide reference laboratory support to test clinical specimens for influenza and identify novel strain.</li> <li>■ Develop and evaluate diagnostic tests for the novel strain.</li> </ul> |



Table 7. (Continued)

| WHO Phase 6: Pandemic Period Actions (no cases in the U.S.) |                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Vaccines and<br>Antiviral drugs                             | <ul style="list-style-type: none"> <li>■ Contract with manufacturers for production of pandemic vaccine.</li> <li>■ Assess candidate vaccines for licensure.</li> <li>■ Review and revise, as needed, priority groups and strategies for antiviral drug use and vaccination.</li> <li>■ Continue ongoing assessment of antiviral resistance of the pandemic strain.</li> </ul>                                                           |
| Healthcare and<br>Emergency Response                        | <ul style="list-style-type: none"> <li>■ Review and revise, as needed, plans for healthcare delivery and community support.</li> <li>■ Assess availability of federal personnel, supplies, and materials for infection control and clinical care of infected patients.</li> <li>■ Provide guidance to healthcare providers on infection control guidelines for hospitals, long-term care facilities, and outpatient settings.</li> </ul> |
| Communications<br>and Outreach                              | <ul style="list-style-type: none"> <li>■ Update stakeholders and the media through regular briefings.</li> <li>■ Educate healthcare providers through satellite broadcasts, webcasts, and other communications channels.</li> <li>■ Continue public education activities.</li> </ul>                                                                                                                                                     |

Table 8: WHO Pandemic Phase 6, U.S. Cases: HHS Actions

| WHO Phase 6: Pandemic Period Actions (cases in the U.S.)                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Planning and<br>Coordination                                                | <ul style="list-style-type: none"> <li>■ Make determination of pandemic disease in the U.S.</li> <li>■ Assess need for funding for costs associated with pandemic response.</li> <li>■ Coordinate with international organizations and foreign governments as well as state and local governments.</li> </ul>                                                                                                                                                                                                                                                                                                                                                          |
| Surveillance,<br>Investigation, and<br>Protective Public<br>Health Measures | <ul style="list-style-type: none"> <li>■ Investigate initial cases and outbreaks; consider/implement interventions to decrease disease spread.</li> <li>■ Implement studies of spread in communities and families; identify risk factors for infection and adverse health outcomes.</li> <li>■ Reassess containment strategies such as travel advisories and restrictions.</li> <li>■ Provide laboratory support to health departments in affected areas.</li> <li>■ Initiate active reporting of enhanced surveillance for mortality and severe morbidity in affected areas.</li> <li>■ Assist state and local health agencies in responding to outbreaks.</li> </ul> |

Table 8. (Continued)

| WHO Phase 6: Pandemic Period Actions (cases in the U.S.) |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|----------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                          | <ul style="list-style-type: none"> <li>■ Consult with state and local public health agencies on implementation of strategies to control disease spread and decrease infection rates in communities, as needed.</li> <li>■ Assess impacts of community control strategies.</li> <li>■ Assess the effectiveness of public health measures and outbreak control.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Vaccines and Antiviral drugs                             | <ul style="list-style-type: none"> <li>■ Review/revise priority populations for vaccination and antiviral drug use.</li> <li>■ Negotiate production and purchase of pandemic vaccine from manufacturers.</li> <li>■ Begin distribution of pandemic vaccine, if available, and immunization of target groups.</li> <li>■ Assist in providing resources and personnel for vaccine administration.</li> <li>■ Monitor vaccine coverage and vaccine adverse events.</li> <li>■ Conduct studies of vaccine effectiveness; re-evaluate vaccine dose and schedule.</li> <li>■ Implement distribution of the antiviral stockpile.</li> <li>■ Monitor antiviral drug distribution and adverse events.</li> <li>■ Conduct studies of antiviral drug impacts.</li> <li>■ Review and approve, as appropriate, IND or EUA applications.</li> </ul> |
| Healthcare and Emergency Response                        | <ul style="list-style-type: none"> <li>■ Advise states and localities to activate plans to coordinate healthcare delivery and community response.</li> <li>■ Deploy medical personnel, equipment, and supplies to augment local healthcare capacity in affected areas.</li> <li>■ Evaluate clinical outcomes and define optimal treatment strategies.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Communications and Outreach                              | <ul style="list-style-type: none"> <li>■ Activate pandemic communications plan.</li> <li>■ Reinforce education on care seeking and home care.</li> <li>■ Communicate lessons learned to healthcare providers and public health agencies on effectiveness of clinical and public health responses.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Research                                                 | <ul style="list-style-type: none"> <li>■ Evaluate effectiveness of vaccine, antiviral drugs, and other interventions.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |

**Table 9: WHO Pandemic Phase 6, Between Pandemic Waves or Pandemic Subsided in the U.S: HHS Actions**

| <b>WHO Phase 6: Pandemic Period Actions<br/>(between pandemic waves or pandemic subsided in the U.S.)</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Planning and Coordination                                                                                 | <ul style="list-style-type: none"> <li>■ Assess coordination during period of pandemic disease and revise response plans, as needed.</li> <li>■ Implement after-action review of pandemic response activities.</li> <li>■ Assess resources and authorities that may be needed for subsequent pandemic waves.</li> </ul>                                                                                                                                                                                                                                                                                                                  |
| Surveillance, Investigation, and Protective Public Health Measures                                        | <ul style="list-style-type: none"> <li>■ Estimate overall pandemic health impacts including mortality and severe morbidity.</li> <li>■ Continue enhanced domestic and international surveillance to detect further pandemic waves.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                            |
| Vaccines and Antiviral drugs                                                                              | <ul style="list-style-type: none"> <li>■ Assess vaccine coverage, effectiveness of targeting to priority groups, and efficiency of distribution and administration; determine number of persons who remain unprotected.</li> <li>■ Assess vaccine efficacy, safety, and impact during the pandemic.</li> <li>■ Determine potential vaccine formulation changes to improve efficacy or supply.</li> <li>■ Monitor continued administration of vaccine to persons not previously protected.</li> <li>■ Assess antiviral effectiveness and safety.</li> <li>■ Evaluate need to expand vaccine and antiviral production capacity.</li> </ul> |
| Healthcare and Emergency Response                                                                         | <ul style="list-style-type: none"> <li>■ Assess effectiveness of federal healthcare and service delivery during prior pandemic phases and revise plans, as needed.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Communications and Outreach                                                                               | <ul style="list-style-type: none"> <li>■ Assess effectiveness of communications during prior pandemic phases and revise plans, as needed.</li> <li>■ Communicate with healthcare providers, the media, and the public about the likely next pandemic wave.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                    |
| Research                                                                                                  | <ul style="list-style-type: none"> <li>■ Evaluate effectiveness of vaccine, antiviral drugs, and other interventions.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

# appendices

---





# appendices

## TABLE OF CONTENTS

|                                                                                                              |      |
|--------------------------------------------------------------------------------------------------------------|------|
| A. National Response Plan .....                                                                              | A-1  |
| B. Pandemic Influenza Background.....                                                                        | B-3  |
| C. WHO Pandemic Phases.....                                                                                  | C-8  |
| D. NVAC/ACIP Recommendations on Use of Vaccines and NVAC Recommendations on Pandemic Antiviral Drug Use..... | D-10 |
| E. Legal Authorities.....                                                                                    | E-30 |
| F. Current Key HHS Activities .....                                                                          | F-33 |
| G. HHS Research Activities .....                                                                             | G-42 |
| H. International Partnership on Avian and Pandemic Influenza.....                                            | H-59 |
| I. Acronym List.....                                                                                         | I-61 |
| J. Internet Resources on Pandemic Influenza .....                                                            | J-63 |



# appendix A: national response plan

An influenza pandemic may require activation of the National Response Plan (NRP), especially if the first appearance of the disease in the United States occurs in one or a few isolated communities and an intense multi-party containment effort led by the federal government seems feasible. The Department of Homeland Security (DHS), in collaboration with HHS and other response partners, developed the NRP and the associated National Incident Management System (NIMS) pursuant to the requirements of Homeland Security Presidential Directive (HSPD) #5 – Management of Domestic Incidents. Full descriptions of the NRP and the NIMS, respectively, are available at [www.dhs.gov/interweb/assetlibrary/NRP\\_FullText.pdf](http://www.dhs.gov/interweb/assetlibrary/NRP_FullText.pdf) and [www.fema.gov/nims/nims\\_compliance.shtm#nimsdocument](http://www.fema.gov/nims/nims_compliance.shtm#nimsdocument).

The intent of the NRP is to reduce America's vulnerability to terrorism, major disasters, and other emergencies; to minimize the damage resulting from these emergencies; and to facilitate recovery. The NIMS aligns the special-purpose incident management and emergency response plans of federal government agencies into a unitary structure. Together, the NRP and the NIMS provide a conceptual and operational framework to integrate the capabilities and resources of various governmental jurisdictions, incident management and emergency response disciplines, nongovernmental organizations (NGOs), and the private sector into a cohesive, coordinated, and seamless national framework for domestic incident management. The federal government can invoke the NRP partially or fully in the context of a threat, anticipation of a significant event, or the response to a significant event.

## Emergency support functions

The NRP applies a functional approach that groups the capabilities of federal government departments and agencies and the American Red Cross into Emergency Support Functions (ESFs) to provide the planning, support, resources, program implementation, and emergency services that are most likely to be needed. The HHS has primary responsibility for implementing ESF #8 – Public Health and Medical Services, which provides the mechanism for coordinated federal government assistance to supplement state, local, and tribal resources in response to public health and medical care needs (to include veterinary and/or animal issues when appropriate) in the face of a potential or actual large-scale public health and medical emergency.



*The intent of the NRP is to reduce America's vulnerability to terrorism, major disasters, and other emergencies; to minimize the damage resulting from these emergencies; and to facilitate recovery.*



**The full set of Emergency Support Functions is as follows:**

|             |                                             |
|-------------|---------------------------------------------|
| ESF1        | Transportation                              |
| ESF2        | Communications                              |
| ESF3        | Public Works and Engineering                |
| ESF4        | Firefighting                                |
| ESF5        | Emergency Management                        |
| ESF6        | Mass Care, Housing, Human Services          |
| ESF7        | Resource Support                            |
| <b>ESF8</b> | <b>Public Health and Medical Services</b>   |
| ESF9        | Urban Search and Rescue                     |
| ESF10       | Oil and Hazardous Materials Response        |
| ESF11       | Agriculture and Natural Resources           |
| ESF12       | Energy                                      |
| ESF13       | Public Safety and Security                  |
| ESF14       | Long-Term Community Recovery and Mitigation |
| ESF15       | External Affairs                            |

ESF #8 provides for supplemental assistance to state, local, and tribal governments in identifying and meeting the public health and medical needs in core functional areas that include assessment of public health and medical needs (including behavioral health); public health surveillance; medical care personnel; fatality management; and medical equipment and supplies. Management of response activities under ESF #8 occurs through the National Response Coordination Center (NRCC), the Interagency Incident Management Group (IIMG), and the Joint Information Center (JIC). Medical response assets internal to HHS (e.g., the U.S. Public Health Service Commissioned Corps) and through ESF #8 supporting organizations (e.g., the Department of Homeland Security's National Disaster Medical System [NDMS]) may be deployed along with assets from the Strategic National Stockpile (SNS). A complete description of ESF #8 actions and authorities is included in the Public Health and Medical Services annex of the NRP.

The Secretary of HHS directs and oversees HHS activities under ESF-8 through the Assistant Secretary for Public Health Emergency Preparedness (ASPHEP). These activities generally include activation of the Incident Management Team (IMT) within the Secretary's Operation Center (SOC), which serves as the focal point for coordination and communication within HHS and with the DHS and other departments and independent agencies. The ASPHEP serves as the Incident Manager. If warranted, the ASPHEP requests HHS Operating Divisions (OPDIVs) to provide individuals to serve on the IMT. OPDIV Emergency Operations Centers (EOCs) are activated in accordance with the magnitude of the response.

The scope and pace of an influenza pandemic may defy accurate prediction. **The disease may appear in many different parts of the Nation almost simultaneously, or disease may occur in only one or a few communities, and if not contained there, proceed to affect other communities.** In either case, the Secretary of HHS may have reason to exercise his authority under the Public Health Service Act to declare a Public Health Emergency prior to or essentially coincident with activation of the NRP.



## appendix B: pandemic influenza background

Pandemics of influenza are extreme infectious disease outbreaks. Although many infectious disease outbreaks (e.g. Severe Acute Respiratory Syndrome [SARS], Ebola, HIV, or West Nile Virus) can cause devastation, these infections are typically limited in their spread to either localized areas or regions, or to at-risk populations. Pandemic influenza, by contrast, is an explosive global event in which most, if not all, populations worldwide are at risk for infection and illness. In past pandemics, influenza viruses have spread worldwide within months and are expected to spread even more quickly today given modern travel patterns.

It is the sheer scope of influenza pandemics, with their potential to rapidly spread and overwhelm societies and cause illnesses and deaths among all age groups, which distinguishes pandemic influenza from other emerging infectious disease threats and makes pandemic influenza one of the most feared emerging infectious disease threats.

### A. Influenza viruses

The agent of pandemic influenza is the influenza virus, which is also responsible for causing seasonal influenza, known by most persons as the flu. Seasonal influenza, a common disease characterized by symptoms such as fever, fatigue, body pain, headache, dry cough, and sore throat, affects large numbers of people each year. Although most people infected with flu recover, it is still responsible for approximately 36,000 deaths and 226,000 hospitalizations each year in the U.S.

Influenza viruses are negative-stranded RNA viruses that have been classified taxonomically as orthomyxoviruses; they are divided into two types: "A" and "B" viruses. Influenza type C is not known to cause disease in humans and so is not applicable to this discussion. The remarkable variation of influenza strains—particularly type A—and their ability to cause annual epidemics of respiratory illness of varying intensity and severity, continue to be the focus of intense investigation. Only type A viruses are known to cause pandemics. Type A viruses are further divided into subtypes based on the specific hemagglutinin (H) and neuraminidase (N) proteins on the virus surface. Currently, two subtypes of A viruses are in worldwide circulation in humans: H3N2 and H1N1. The emergence of both of these subtypes in the 20th century led to separate pandemics. For example, the 1918 pandemic resulted from the emergence and spread of the H1N1 virus while the 1968 pandemic was associated with the H3N2 virus. The 1957 pandemic was associated with the emergence and spread of the H2N2 virus; however, this virus subtype stopped circulating in 1968. **Influenza pandemics are believed to have occurred for at least 300 years at unpredictable intervals.**

*Pandemic influenza ... is an explosive global event in which most, if not all, populations worldwide are at risk for infection and illness.*

## B. Why influenza pandemics occur

### 1. Drift and shift

An important feature of influenza viruses that helps to explain much of their epidemiological patterns is the ability and propensity of these viruses to modify (drift) or replace (shift) two key viral proteins, hemagglutinin and neuraminidase, on the viral surface. Because these proteins are the main targets for the immune system, changes in these proteins can have minor to profound effects on the antigenicity of influenza viruses.

#### a) Drift

Influenza viruses can change through antigenic drift, which is a process in which mutations to the virus genome produce changes in the viral H or N. Drift is a continuous ongoing process that results in the emergence of new strain variants. The amount of change can be subtle or dramatic, but eventually one of the new variant strains becomes dominant, usually for a few years, until a new variant emerges and replaces it. In essence, drift affects the influenza viruses that are already in worldwide circulation. This process allows influenza viruses to change and re-infect people repeatedly through their lifetime and is the reason the influenza virus strains in vaccine must be updated each year.

#### b) Shift

In contrast to drift, pandemic viruses arise through a process known as antigenic shift. In this process, the surface existing viral H and N proteins are not modified, but are replaced by significantly different H and Ns. Since influenza A viruses that bear new (or novel) H or H/N combinations are perceived by immune systems as new, most people do not have pre-existing antibody protection to these novel viruses. This is one of the reasons that pandemic viruses can have such severe impact on the health of populations.

## C. Animal reservoirs

Novel influenza viruses occasionally emerge among humans as part of the natural ecology and biology of influenza viruses. Wild birds are considered the reservoir for influenza viruses because more influenza A subtypes (15) circulate among wild birds than humans or other animal species. Normally, animal influenza viruses do not infect humans. However, avian influenza viruses can sometimes cross this barrier and directly infect humans. This was demonstrated in 1997, when an outbreak of avian influenza A (H5N1) viruses infected both domestic poultry and humans in Hong Kong, leading to 18 hospitalizations and 6 deaths. Since then, other outbreaks of avian viruses (such as H9N2 in 1999, H7N2 in 2002, H7N7 in 2003, and H5N1 again in 2004) have occurred and been found to directly infect people. Fortunately, these avian viruses lacked the ability to spread easily from person-to-person and therefore did not precipitate larger outbreaks or a pandemic.

Pandemic viruses can also arise when some of the genes from animal influenza viruses mix or reassort with some of the genes from human influenza viruses to create a new hybrid influenza virus. This can occur when a single animal (for example, a pig or possibly a person) is simultaneously co-infected by both a human influenza virus and an avian influenza virus. In this situation, genes from the human and avian viruses can reassort and create a virus with the surface proteins derived from the avian virus (hence, creating a new subtype) and the internal proteins derived from the human virus, enhancing the transmissibility of the hybrid virus. The process of reassortment is not theoretical. Reassorted viruses have been frequently identified and are thought to have been responsible for the 1957 and 1968 pandemic viruses.

#### D. Distinguishing pandemic from seasonal influenza

Several epidemiological features distinguish pandemic influenza from seasonal influenza. Pandemics of influenza are unusual events and their timing cannot be predicted. For example, only three pandemics occurred in the 20th century (1918, 1957, and 1968). The infrequency and unpredictable timing of these events is explained by the fact that influenza pandemics occur only when a new (or novel) influenza A virus emerges and spreads globally. By definition, most people have never been exposed to these viruses and therefore are susceptible to infection by them. In contrast, seasonal influenza virus strain variants are modified versions of influenza A viruses that are already in widespread circulation. Therefore, there is usually some level of pre-existing immunity to strain variants. Because of the frequent appearance of new variants, virus strains contained in seasonal interpandemic trivalent influenza vaccines must be updated annually.



*Influenza pandemics occur only when a new (or novel) influenza A virus emerges and spreads globally.*

*It is clear that pandemic influenza has the potential to pose disease control challenges unmatched by any other natural or intentional infectious disease event.*

## E. Impact of influenza and influenza pandemics

An annual influenza season in the U.S., on average, results in approximately 36,000 deaths, 226,000 hospitalizations, and between \$1 billion and \$3 billion in direct costs for medical care. This impact occurs because influenza infections result in secondary complications such as pneumonia, dehydration, and worsening of chronic lung and heart problems. Despite the severity of influenza epidemics, it is sobering to understand that the effects of seasonal influenza are moderated because most individuals have some underlying degree of immunity to recently circulating influenza viruses either from previous infections or from vaccination.

It is clear that pandemic influenza has the potential to pose disease control challenges unmatched by any other natural or intentional infectious disease event. Pandemic influenza viruses have demonstrated their ability to spread worldwide within months, or weeks, and to cause infections in all age groups. While the ultimate number of infections, illnesses, and deaths is unpredictable, and could vary tremendously depending on multiple factors, it is nonetheless certain that without adequate planning and preparations, an influenza pandemic in the 21st century has the potential to cause enough illnesses to overwhelm current public health and medical care capacities at all levels, despite the vast improvements made in medical technology during the 20th century.

### **Certain modern trends could increase the potential for pandemics to cause more illnesses and deaths than occurred in earlier pandemics:**

- First, the global population is larger and increasingly urbanized, allowing viruses to be transmitted within populations more easily.
- Second, levels of international travel are much greater than in the past, allowing viruses to spread globally more quickly than in the past.
- Third, populations in many countries consist of increasing numbers of elderly persons and those with chronic medical conditions, thus increasing the potential for more complicated illnesses and deaths to occur.

This combination of factors suggests that the next pandemic may lead to more illnesses occurring more quickly than in the past, overwhelming countries and health systems that are not adequately prepared.

The 1957 pandemic, during an era with much less globalization, spread to the U.S. within 4–5 months of its detection in China, and the 1968 pandemic spread to the U.S. from Hong Kong within 2–3 months. As was amply demonstrated by the SARS outbreak, modern travel patterns may significantly reduce the time needed for pandemic influenza viruses to spread globally to a few months or even weeks. The major implication of such rapid spread of an infectious disease is that many, if not most, countries will have minimal time to implement preparations and responses once pandemic viruses have begun to spread. While SARS infections spread quickly to multiple countries, the epidemiology and transmission modes of the SARS virus greatly helped to contain the spread of this infection in 2003, along with quarantine, isolation, and other control measures. Fortunately, no widespread community transmission took place. By contrast, because influenza spreads more rapidly between

**Table B-1: Effects of Past Pandemics on the U.S.**

| <b>Pandemic</b> | <b>Estimated U.S. Deaths</b> | <b>Influenza A Strain</b> | <b>Populations at greatest risk</b> |
|-----------------|------------------------------|---------------------------|-------------------------------------|
| 1918-1919       | 500,000                      | H1N1                      | Young, healthy adults               |
| 1957-1958       | 70,000                       | H2N2                      | Infants, elderly                    |
| 1968-1969       | 34,000                       | H3N2                      | Infants, elderly                    |

people and can be transmitted by those who are infected but do not yet have symptoms, the spread of pandemic influenza to multiple countries is expected to lead to the near simultaneous occurrence of multiple community outbreaks in an escalating fashion. No other infectious disease threat, whether natural or engineered, poses the same current threat for causing increases in infections, illnesses, and deaths so quickly in the U.S. and worldwide.

## **F. H5N1 avian influenza**

Although it is unpredictable when the next pandemic will occur and what strain may cause it, the continued and expanded spread of a highly pathogenic—and now endemic—avian H5N1 virus across much of eastern Asia, Russia, and eastern Europe represents a significant pandemic threat. Human avian H5N1 influenza infection was first recognized in 1997 when it infected 18 people in Hong Kong, causing 6 deaths. Concern has increased in recent years as avian H5N1 infections have killed poultry flocks in countries throughout Asia and in parts of Europe. Since 2003, over 100 human H5N1 cases have been diagnosed in Thailand, Vietnam, Cambodia, and Indonesia. The H5N1 virus circulating in Asia has raised concerns about the potential for a pandemic because:

- The avian H5N1 virus is widespread and endemic in much of Asia with spread to Russia and Europe.
- The avian H5N1 virus is becoming more deadly in a growing number of bird species and mammals.
- Wild birds and domestic ducks may be infected asymptomatically, providing a reservoir for infection of other domestic poultry species.
- The virus is able to transmit directly from birds to some mammals and in some circumstances to people.
- There is sporadic spread directly from animals to humans with suspected human-to-human transmission in rare instances.
- Genetic studies confirm that H5N1, like other influenza viruses, is continuing to change and evolve.

While H5N1 is the greatest current pandemic threat, other avian influenza subtypes have also infected people in recent years. In 1999, H9N2 infections were identified in Hong Kong; in 2003, H7N7 infections occurred in the Netherlands; and in 2004, H7N3 infections occurred in Canada. Such outbreaks have the potential to give rise to the next pandemic, reinforcing the need for continued surveillance and ongoing vaccine development efforts against these strains.





## appendix C: WHO pandemic phases

In 1999, the World Health Organization (WHO) Secretariat published guidance for pandemic influenza and defined the phases of a pandemic. Updated guidance was published in 2005 to redefine these phases. This schema is designed to provide guidance to the international community and to national governments on preparedness and response for pandemic threats and pandemic disease. Compared with the 1999 phases, the new definitions place more emphasis on pre-pandemic phases when pandemic threats may exist in animals or when new influenza virus subtypes infect people but do not spread efficiently. Recognizing that distinctions between the two interpandemic phases and the three pandemic alert phases may be unclear, the WHO Secretariat proposes to base classification on assessment of risk based on a range of scientific and epidemiological data.

**Table C-1: Summary of WHO Global Pandemic Phases (WHO Global Influenza Preparedness Plan, 2005)**

### Interpandemic Period

- Phase 1.** No new influenza virus subtypes have been detected in humans. An influenza virus subtype that has caused human infection may be present in animals. If present in animals, the risk of human infection or disease is considered to be low
- Phase 2.** No new influenza virus subtypes have been detected in humans. However, a circulating animal influenza virus subtype poses a substantial risk of human disease

### Pandemic Alert Period

- Phase 3.** Human infection(s) with a new subtype but no human-to-human spread or at most rare instances of spread to a close contact
- Phase 4.** Small cluster(s) with limited human-to-human transmission but spread is highly localized, suggesting that the virus is not well adapted to humans
- Phase 5.** Larger cluster(s) but human-to-human spread is still localized, suggesting that the virus is becoming increasingly better adapted to humans but may not yet be fully transmissible (substantial pandemic risk)

### Pandemic Period

- Phase 6.** Pandemic phase: increased and sustained transmission in the general population

### Postpandemic Period

Return to the Interpandemic Period (Phase 1)

<sup>1</sup> <http://www.who.int/csr/resources/publications/influenza/whocdscsredc991.pdf>

<sup>2</sup> [http://www.who.int/csr/resources/publications/influenza/WHO\\_CDS\\_CSR\\_GIP\\_2005\\_5.pdf](http://www.who.int/csr/resources/publications/influenza/WHO_CDS_CSR_GIP_2005_5.pdf)



Recognizing that at any pandemic phase, national situations will differ based on whether a country is affected or not affected by the novel influenza subtype, the WHO Secretariat recommends "national subdivisions" of phases based on whether a country is experiencing disease or has extensive trade and travel links with an affected country. National subdivisions of phases will be designated by national authorities. In the United States, pandemic phases will be defined based on the global phase and determined by the Secretary of Health and Human Services. During the pandemic phase, additional subdivisions may be defined based on the extent of disease. In actual practice, the distinction between the various phases of pandemic influenza may be blurred or occur in a matter of hours, again underscoring the need for flexibility.





## **appendix D: NVAC/ACIP recommendations for prioritization of pandemic influenza vaccine and NVAC recommendations on pandemic antiviral drug use**

*Advisory Committee recommendations ... provide guidance for planning purposes and form the basis for further discussion of how to equitably allocate medical countermeasures that will be in short supply early in an influenza pandemic.*

Advisory Committee recommendations are presented in this report to provide guidance for planning purposes and to form the basis for further discussion of how to equitably allocate medical countermeasures that will be in short supply early in an influenza pandemic.

Two federal advisory committees, the Advisory Committee on Immunization Practices (ACIP) and the National Vaccine Advisory Committee (NVAC), provided recommendations to the Department of Health and Human Services on the use of vaccines and antiviral drugs in an influenza pandemic.

Although the advisory committees considered potential priority groups broadly, the main expertise of the members was in health and public health. The primary goal of a pandemic response considered was to decrease health impacts including severe morbidity and death; secondary pandemic response goals included minimizing societal and economic impacts. However, as other sectors are increasingly engaged in pandemic planning, additional considerations may arise. The advisory committee reports explicitly acknowledge the importance of this, for example highlighting the priority for protecting critical components of the military. Finally, HHS has recently initiated outreach to engage the public and obtain a broader perspective into decisions on priority groups for pandemic vaccine and antiviral drugs. Though findings of the outreach are preliminary, a theme that has emerged is the importance of limiting the effects of a pandemic on society by preserving essential societal functions.



Based on this guidance, state, local, and tribal implementation plans should be developed to 1) include more specific definitions of the priority groups (e.g., which functions are indeed critical to maintaining continuity) and their size; 2) define how persons in these groups will be identified; and 3) establish strategies for effectively and equitably delivering vaccines and antiviral drugs to these populations. The committees acknowledged that further work is needed, in particular, to identify the functions that must be preserved to maintain effective services and critical infrastructures and to identify the groups that should be protected to achieve this goal. The committees also acknowledge that the specific composition of some priority groups may differ between states or localities based on their needs and that priority groups should be reconsidered when a pandemic occurs and information is obtained on its epidemiology and impacts.



On July 19, 2005, ACIP and NVAC voted unanimously in favor of the vaccine priority recommendations summarized in Table D-1. These votes followed deliberations of a joint Working Group of the two committees, which included as consultants representatives of public and private sector stakeholder organizations and academic experts. There was limited staff level participation from DoD, DHS, and VA. Several ethicists also served as consultants to the Working Group.

## A. Critical assumptions

The recommendations summarized in Table D-1 were based on the following critical assumptions:

- **Morbidity and mortality.** The greatest risk of hospitalization and death—as during the 1957 and 1968 pandemics and annual influenza—will be in infants, the elderly, and those with underlying health conditions. In the 1918 pandemic, most deaths occurred in young adults, highlighting the need to reconsider the recommendations at the time of the pandemic based on the epidemiology of disease.
- **Healthcare system.** The healthcare system will be severely taxed if not overwhelmed due to the large number of illnesses and complications from influenza requiring hospitalization and critical care. CDC models estimate increases in hospitalization and intensive care unit demand of more than 25% even in a moderate pandemic.
- **Workforce.** During a pandemic wave in a community, between 25% and 30% of persons will become ill during a 6 to 8 week outbreak. Among working-aged adults, illness attack rates will be lower than in the community as a whole. A CDC model suggests that at the peak of pandemic disease, about 10% of the workforce will be absent due to illness or caring for an ill family member. Impacts will likely vary between communities and work sites and may be greater if significant absenteeism occurs because persons stay home due to fear of becoming infected.
- **Critical infrastructure.** Only limited information was available from which to assess potential impacts on critical infrastructure sectors such as transportation and utility services. Because of changes in business practices and the complexity of networks, information from prior pandemics was not considered applicable.
- **Vaccine production capacity.** The U.S.-based vaccine production capacity was assumed at 3 to 5 million 15µg doses per week with 3 to 6 months needed before the first doses are produced. Two doses per person were assumed to be required for protection. Subsequent results of an NIH clinical trial of influenza A (H5N1) vaccine suggest that higher doses of antigen will be needed to elicit a good immune response; thus, the assumptions made by the committee could potentially substantially exceed the amount of vaccine that would be produced.

Table D-1: Vaccine Priority Group Recommendations\*

| Tier | Subtier | Population                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Rationale                                                                                                                                                                                                                                                                                                                                                                                                 |
|------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1    | A       | <ul style="list-style-type: none"> <li>■ Vaccine and antiviral manufacturers and others essential to manufacturing and critical support (~40,000)</li> <li>■ Medical workers and public health workers<sup>3</sup> who are involved in direct patient contact, other support services essential for direct patient care, and vaccinators (8-9 million)</li> </ul>                                                                                                                                                 | <ul style="list-style-type: none"> <li>■ Need to assure maximum production of vaccine and antiviral drugs</li> <li>■ Healthcare workers are required for quality medical care (studies show outcome is associated with staff-to-patient ratios). There is little surge capacity among healthcare sector personnel to meet increased demand.</li> </ul>                                                    |
|      | B       | <ul style="list-style-type: none"> <li>■ Persons ≥ 65 years with 1 or more influenza high-risk conditions, not including essential hypertension (approximately 18.2 million)</li> <li>■ Persons 6 months to 64 years with 2 or more influenza high-risk conditions, not including essential hypertension (approximately 6.9 million)</li> <li>■ Persons 6 months or older with history of hospitalization for pneumonia or influenza or other influenza high-risk condition in the past year (740,000)</li> </ul> | <ul style="list-style-type: none"> <li>■ These groups are at high risk of hospitalization and death. Excludes elderly in nursing homes and those who are immunocompromised and would not likely be protected by vaccination</li> </ul>                                                                                                                                                                    |
|      | C       | <ul style="list-style-type: none"> <li>■ Pregnant women (approximately 3.0 million)</li> <li>■ Household contacts of severely immunocompromised persons who would not be vaccinated due to likely poor response to vaccine (1.95 million with transplants, AIDS, and incident cancer x 1.4 household contacts per person = 2.7 million persons)</li> <li>■ Household contacts of children &lt;6 month olds (5.0 million)</li> </ul>                                                                               | <ul style="list-style-type: none"> <li>■ In past pandemics and for annual influenza, pregnant women have been at high risk; vaccination will also protect the infant who cannot receive vaccine.</li> <li>■ Vaccination of household contacts of immunocompromised and young infants will decrease risk of exposure and infection among those who cannot be directly protected by vaccination.</li> </ul> |
|      | D       | <ul style="list-style-type: none"> <li>■ Public health emergency response workers critical to pandemic response (assumed one-third of estimated public health workforce=150,000)</li> <li>■ Key government leaders</li> </ul>                                                                                                                                                                                                                                                                                     | <ul style="list-style-type: none"> <li>■ Critical to implement pandemic response such as providing vaccinations and managing/monitoring response activities</li> <li>■ Preserving decision-making capacity also critical for managing and implementing a response</li> </ul>                                                                                                                              |

<sup>3</sup> This is inclusive of federal healthcare providers to Indian nations and tribes.



Table D-1. Continued

| Tier | Subtier | Population                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Rationale                                                                                                                                                                                                                      |
|------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2    | A       | <ul style="list-style-type: none"> <li>■ Healthy 65 years and older (17.7 million)</li> <li>■ 6 months to 64 years with 1 high-risk condition (35.8 million)</li> <li>■ 6-23 months old, healthy (5.6 million)</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                             | ■ Groups that are also at increased risk but not as high risk as population in Tier 1B                                                                                                                                         |
|      | B       | <ul style="list-style-type: none"> <li>■ Other public health emergency responders (300,000 = remaining two-thirds of public health work force)</li> <li>■ Public safety workers including police, fire, 911 dispatchers, and correctional facility staff (2.99 million)</li> <li>■ Utility workers essential for maintenance of power, water, and sewage system functioning (364,000)</li> <li>■ Transportation workers transporting fuel, water, food, and medical supplies as well as public ground public transportation (3.8 million)</li> <li>■ Telecommunications/IT for essential network operations and maintenance (1.08 million)</li> </ul> | ■ Includes critical infrastructure groups that have impact on maintaining health (e.g., public safety or transportation of medical supplies and food); implementing a pandemic response; and on maintaining societal functions |
| 3    |         | <ul style="list-style-type: none"> <li>■ Other key government health decision-makers (estimated number not yet determined)</li> <li>■ Funeral directors/embalmers (62,000)</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | ■ Other important societal groups for a pandemic response but of lower priority                                                                                                                                                |
| 4    |         | <ul style="list-style-type: none"> <li>■ Healthy persons 2-64 years not included in above categories (179.3 million)</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | ■ All persons not included in other groups based on objective to vaccinate all those who want protection                                                                                                                       |

\*The committee focused its deliberations on the U.S. civilian population. ACIP and NVAC recognize that Department of Defense needs should be highly prioritized. DoD Health Affairs indicates that 1.5 million service members would require immunization to continue current combat operations and preserve critical components of the military medical system. Should the military be called upon to support civil authorities domestically, immunization of a greater proportion of the total force will become necessary. These factors should be considered in the designation of a proportion of the initial vaccine supply for the military.

Other groups also were not explicitly considered in these deliberations on prioritization. These include American citizens living overseas, non-citizens in the U.S., and other groups providing national security services such as the border patrol and customs service.

## B. Definitions and rationales for priority groups

### 1. Healthcare workers and essential healthcare support staff

#### a) Definition

Healthcare workers (HCW) with direct patient contact (including acute-care hospitals, nursing homes, skilled nursing facilities, urgent care centers, physician's offices, clinics, home care, blood collection centers, and EMS) and a proportion of persons working in essential healthcare support services needed to maintain healthcare services (e.g. dietary, housekeeping, admissions, blood collection center staff, etc.). Also included are healthcare workers in public health with direct patient contact, including those who may administer vaccine or distribute influenza antiviral medications, and essential public health support staff for these workers.

#### b) Rationale

The pandemic is expected to have substantial impact on the healthcare system with large increases in demand for healthcare services placed on top of existing demand. HCW will be treating influenza-infected patients and will be at risk of repeated exposures. Further, surge capacity in this sector is low. To encourage continued work in a high-exposure setting and to help lessen the risk of healthcare workers transmitting influenza to other patients and HCW family members, this group was highly prioritized. In addition, increases in bed/nurse ratios have been associated with increases in overall patient mortality. Thus, substantial absenteeism may affect overall patient care and outcomes.

### 2. Groups at high risk of influenza complications

#### a) Definition

Persons 2–64 years with a medical condition for which influenza vaccine is recommended and all persons 6–23 months and 65 years and older. Excludes nursing home residents and severely immunocompromised persons who would not be expected to respond well to vaccination.

#### b) Rationale

These groups were prioritized based on their risk of influenza-related hospitalization and death and also their likelihood of vaccine response. Information from prior pandemics was used whenever possible, but information from interpandemic years was also considered. Nursing home residents and severely immunocompromised persons would be prioritized for antiviral treatment and/or prophylaxis and vaccination of healthcare workers and household contacts who are most likely to transmit influenza to these high risk groups.

### 3. Critical infrastructure

#### a) Definitions and rationale

Those critical infrastructure sectors that fulfill one or more of the following criteria: have increased demand placed on them during a pandemic, directly support reduction in deaths and hospitalization; function is critical to support the healthcare sector and other emergency services, and/or supply basic





necessities and services critical to support of life and healthcare or emergency services. Groups included in critical infrastructure are needed to respond to a pandemic and to minimize morbidity and mortality, and include the following sectors:

- Persons directly involved with influenza vaccine and antiviral medication manufacturing and distribution and essential support services and suppliers (e.g., growers of pathogen-free eggs for growth of vaccine virus) production activities
- Key government leaders and health decision-makers who will be needed to quickly move policy forward on pandemic prevention and control efforts
- Public safety workers (firefighters, police, and correctional facility staff, including dispatchers) are critical to maintaining social functioning and order and will contribute to a pandemic response, for example by ensuring order at vaccination clinics and responding to medical emergencies
- Utility service workers (water, power, and sewage management) are prioritized as the services they provide are also essential to the healthcare system as well as to preventing additional illnesses from lack of these services unrelated to a pandemic.
- Transportation workers who maintain critical supplies of food, water, fuel, and medical equipment and who provide public transportation, which is essential for provision of medical care and transportation of healthcare workers to work and transportation of ill persons for care
- Telecommunication and information technology services critical for maintenance and repairs of these systems are also essential as these systems are now critical for accessing and delivering medical care and in support of all other critical infrastructure.
- Mortuary services will be substantially impacted due to the increased numbers of deaths from a pandemic and the fact that impact will be high in the elderly, a growing segment of the population

#### 4. Public health emergency response workers

##### a) Definition

This group includes persons who do not have direct patient care duties, but who are essential for surveillance for influenza, assessment of the pandemic impact, allocation of public health resources for the pandemic response, development and implementation of public health policy as part of the response, and development of guidance as the pandemic progresses.

##### b) Rationale

Persons in this sector have been critical for past influenza vaccine pandemics and influenza vaccine shortages and little surge capacity may be available during a public health emergency such as a pandemic.

#### 5. Persons in skilled nursing facilities

##### a) Definition

Patients residing in skilled nursing facilities. Not included in this group are persons in other residential settings (e.g., assisted living) who are more likely to be mobile, in a setting that is less closed, and have decentralized healthcare.

##### b) Rationale

This group was not prioritized for vaccine because of the medical literature finding poor response to vaccination and occurrence of outbreaks even in the setting of high vaccination rates. Other studies have suggested that vaccination of healthcare workers may be a more effective strategy to prevent influenza in this group. Further, surveillance for influenza can be conducted in this group and antiviral medications used widely for prophylaxis and treatment. Ill visitors and staff should also be restricted from visiting nursing home facilities during outbreaks of pandemic influenza.

This strategy for pandemic influenza vaccine differs from the interpandemic vaccination strategy of aggressively vaccinating nursing home residents. The rationale considers several factors: 1) these populations are less likely to benefit from vaccine than other groups who are also at high risk; 2) other prevention strategies feasible for this group are not possible among other high-risk groups; 3) the overall morbidity and mortality from pandemic is likely to severely impact other groups of persons who would be expected to have a better response to the vaccine; and 4) a more severe shortage of vaccine is anticipated.

#### 6. Severely immunocompromised persons

##### a) Definition

Persons who are undergoing or who have recently undergone bone marrow transplantation and others with severe immunodeficiency (e.g., AIDS patients with CD4 counts <50, children with SCID syndrome, recent bone marrow transplant patients). The numbers of persons in these categories is likely much smaller than the anticipated number assumed in tiering above, but sources for more specific estimates have not been identified.

#### b) Rationale

These groups have a lower likelihood of responding to influenza vaccination. Thus, strategies to prevent severe influenza illness in this group should include vaccination of healthcare workers and household contacts of severely immunocompromised persons and use of antiviral medications. Consideration should be given to prophylaxis of severely immunocompromised persons with influenza antivirals and early antiviral treatment should they become infected.

### 7. Children <6 months of age

#### a) Rationale

Influenza vaccine is poorly immunogenic in children <6 months and the vaccine is currently not recommended for this group. In addition, influenza antiviral medications are not FDA-approved for use in children <1 year old. Thus, vaccination of household contacts and out-of-home caregivers of children <6 months is recommended to protect this high-risk group.

## C. Other discussion

There was substantial discussion on priority for children. Four potential reasons were raised for making vaccination of children a priority:

- At the public engagement session, many participants felt that children should have high priority for vaccination.
- Children play a major role in transmitting infection, and vaccinating this group could slow the spread of disease and indirectly protect others.
- Children have strong immune systems and will respond well to vaccine whereas vaccination of the elderly and those with illnesses may be less effective.
- Some ethical frameworks would support a pediatric priority.

ACIP and NVAC did not make children a priority (other than those included in tiers, because of their underlying diseases [Tiers 1B and 2A] or as contacts of high-risk persons [Tier 1C]) for several reasons:

- Healthy children have been at low risk for hospitalization and death in prior pandemics and during annual influenza seasons.
- It is uncertain whether vaccination of children will decrease transmission and indirectly protect others. Studies that show this impact or mathematical models that predict it rely on high vaccination coverage that may not be possible to achieve given limited supplies in a pandemic.
- The committees recognize that this is an area for further scientific work; that children may be a good target population for live-attenuated influenza vaccine (FluMist®) if it is available; and that education of the public will be needed to provide the rationale for the recommendations.



*NVAC recognizes that recommendations [for antiviral drug use] will need to be reconsidered at the time of a pandemic when information on the available drug supply, epidemiology of disease, and impacts on society are known.*

*The committee considered the primary goal of a pandemic response to decrease health impacts including severe morbidity and death. Minimizing societal and economic impacts were considered secondary and tertiary goals.*

## NVAC RECOMMENDATIONS ON PANDEMIC ANTIVIRAL DRUG USE

On July 19, 2005, NVAC voted unanimously in favor of the antiviral drug use priority recommendations described here and summarized in Table D-2. These votes followed deliberations of a Working Group, which included as consultants representatives of public and private sector stakeholder organizations and academic experts. There was limited staff level participation from DoD, DHS, and VA. Several ethicists also served as consultants to the Working Group.

The recommendations were made considering pandemic response goals, assumptions on the impacts of a pandemic, and after thorough review of past pandemics, annual influenza disease, data on antiviral drug impacts, and recommendations for pandemic vaccine use.

Recommendations were made to guide planning needed for effective implementation at state and local levels. The committee recognizes that recommendations will need to be reconsidered at the time of a pandemic when information on the available drug supply, epidemiology of disease, and impacts on society are known.

The committee considered the primary goal of a pandemic response to decrease health impacts including severe morbidity and death. Minimizing societal and economic impacts were considered secondary and tertiary goals.

## A. Critical assumptions

Assumptions regarding groups at highest risk during a pandemic and impacts on the healthcare system and other critical infrastructures are the same as those underlying the vaccine priority recommendations. Additional assumptions specific for antiviral drugs included:

- Treatment with a neuraminidase inhibitor (oseltamivir [Tamiflu®] or zanamivir [Relenza®]) will be effective in decreasing risk of pneumonia, will decrease hospitalization by about half (as shown for inter pandemic influenza), and will also decrease mortality.
- Antiviral resistance to the adamantanes (amantadine and rimantadine) may limit their use during a pandemic.
- The primary source of antiviral drugs for a pandemic response will be the supply of antiviral drugs that have been stockpiled. Before annual influenza seasons about 2 million treatment courses of oseltamivir are available in the U.S. U.S.-based production of oseltamivir is being established; expected capacity is projected at about 1.25 million courses per month.
- Treating earlier after the onset of disease is most effective in decreasing the risk of complications and shortening illness duration. Generally, treatment should be given within the first 48 hours.
- Assumptions for the amount of antiviral drug needed for defined priority groups is based on the population in those groups and assumptions that 35% of persons in the priority groups will have influenza-like illness and 75% will present within the first 48 hours and be eligible for treatment. For persons admitted to the hospital, the committee assumed that 80% would be treated, as the 48-hour limit may sometimes be relaxed in more ill patients.
- Unlike vaccines, where each tier would be protected in turn as more vaccine is produced, for antiviral drugs, the number of priority groups that can be covered would be known at the start of the pandemic based on the amount of drug that is stockpiled. Additional supply that would become available during the pandemic could provide some flexibility.



**Table D-2: Antiviral Drug Priority Group Recommendations\***

|    | Group                                                                                                                                                                   | Estimated population (millions) | Strategy** | # Courses (millions) |            | Rationale                                                                                                                                            |
|----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|------------|----------------------|------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
|    |                                                                                                                                                                         |                                 |            | For target group     | Cumulative |                                                                                                                                                      |
| 1  | Patients admitted to hospital***                                                                                                                                        | 10.0                            | T          | 7.5                  | 7.5        | Consistent with medical practice and ethics to treat those with serious illness and who are most likely to die                                       |
| 2  | Health care workers (HCW) with direct patient contact and emergency medical service (EMS) providers <sup>4</sup>                                                        | 9.2                             | T          | 2.4                  | 9.9        | Healthcare workers are required for quality medical care. There is little surge capacity among healthcare sector personnel to meet increased demand. |
| 3  | Highest risk outpatients—immunocompromised persons and pregnant women                                                                                                   | 2.5                             | T          | 0.7                  | 10.6       | Groups at greatest risk of hospitalization and death; immunocompromised cannot be protected by vaccination.                                          |
| 4  | Pandemic health responders (public health, vaccinators, vaccine and antiviral manufacturers), public safety (police, fire, corrections), and government decision-makers | 3.3                             | T          | 0.9                  | 11.5       | Groups are critical for an effective public health response to a pandemic.                                                                           |
| 5  | Increased risk outpatients—young children 12-23 months old, persons ≥ 65 yrs old, and persons with underlying medical conditions                                        | 85.5                            | T          | 22.4                 | 33.9       | Groups are at high risk for hospitalization and death.                                                                                               |
| 6  | Outbreak response in nursing homes and other residential settings                                                                                                       | NA                              | PEP        | 2.0                  | 35.9       | Treatment of patients and prophylaxis of contacts is effective in stopping outbreaks; vaccination priorities do not include nursing home residents   |
| 7  | HCWs in emergency departments, intensive care units, dialysis centers, and EMS providers                                                                                | 1.2                             | P          | 4.8                  | 40.7       | These groups are most critical to an effective healthcare response and have limited surge capacity. Prophylaxis will best prevent absenteeism.       |
| 8  | Pandemic societal responders (e.g., critical infrastructure groups as defined in the vaccine priorities) and HCW without direct patient contact                         | 10.2                            | T          | 2.7                  | 43.4       | Infrastructure groups that have impact on maintaining health, implementing a pandemic response, and maintaining societal functions                   |
| 9  | Other outpatients                                                                                                                                                       | 180                             | T          | 47.3                 | 90.7       | Includes others who develop influenza and do not fall within the above groups                                                                        |
| 10 | Highest risk outpatients                                                                                                                                                | 2.5                             | P          | 10.0                 | 100.7      | Prevents illness in the highest risk groups for hospitalization and death.                                                                           |
| 11 | Other HCWs with direct patient contact                                                                                                                                  | 8.0                             | P          | 32.0                 | 132.7      | Prevention would best reduce absenteeism and preserve optimal function.                                                                              |

\* This is inclusive of Federal healthcare providers to Indian Nations and Tribes.

## B. Definitions and rationale for draft priority groups

### 1. Persons admitted to hospital with influenza infection

#### a) Definition

Persons admitted to acute care facilities (traditional or non-traditional with a clinical diagnosis of influenza; laboratory confirmation not required). Excludes persons admitted for a condition consistent with a bacterial superinfection (e.g., lobar pneumonia developing late after illness onset) or after viral replication and shedding has ceased (e.g., as documented by a negative sensitive antigen detection test)

#### b) Strategy

Treatment within 48 hours of system onset.

#### c) Rationale

This group is at greatest risk for severe morbidity and mortality. Although there are no data to document the impacts of antiviral drug treatment among persons who already suffer more severe influenza illness, benefit is biologically plausible in persons with evidence of ongoing virally-mediated pathology (e.g., diffuse pneumonia, ARDS). Providing treatment to those who are most ill is also consistent with standard medical practices, would be feasible to implement, and would be acceptable to the public.

#### d) Population size

The number of persons admitted to hospital in an influenza pandemic would vary substantially depending on the severity of the pandemic and on the ability to expand inpatient capacity, if needed.

#### e) Unresolved issues

More specific guidance should be provided to healthcare workers on implementing antiviral treatment, including when and when not to treat. In some persons with severe illness, the ability to take oral medication or its absorption may be important issues. For infants <1 year old admitted to hospital,

\*The committee focused its deliberations on the domestic U.S. civilian population. NVAC recognizes that Department of Defense (DoD) needs should be highly prioritized. A separate DoD antiviral stockpile has been established to meet those needs. Other groups also were not explicitly considered in deliberations on prioritization. These include American citizens living overseas, non-citizens in the U.S., and other groups providing national security services such as the border patrol and customs service.

\*\*Strategy: Treatment (T) requires a total of 10 capsules and is defined as 1 course. Post-exposure prophylaxis (PEP) also requires a single course. Prophylaxis (P) is assumed to require 40 capsules (4 courses) though more may be needed if community outbreaks last for a longer period.

\*\*\*There are no data on the effectiveness of treatment at hospitalization. If stockpiled antiviral drug supplies are very limited, the priority of this group could be reconsidered based on the epidemiology of the pandemic and any additional data on effectiveness in this population.





decisions about whether to treat with antiviral drugs may depend on the child's age and potential risk versus benefit as the neuraminidase inhibitors are not licensed for use in infants. If possible, data on time from symptom onset to hospital admission, current use of antiviral drug treatment among inpatients, and its impacts should be collected during interpandemic influenza seasons.

## 2. Healthcare workers and emergency medical service providers who have direct patient contact

### a) Definition

Persons providing direct medical services in inpatient and outpatient care settings. Includes doctors, nurses, technicians, therapists, EMS providers, laboratory workers, other care providers who come within 3 feet of patients with influenza, and persons performing technical support functions essential to quality medical care.

### b) Strategy

Treatment within 48 hours of symptom onset.

### c) Rationale

Maintaining high quality patient care is critical to reduce health impacts of pandemic disease and to prevent adverse outcomes from other health conditions that will present for care during the pandemic period. Treatment of healthcare providers will decrease absenteeism due to influenza illness and may decrease absenteeism from fear of becoming ill, given the knowledge that treatment can prevent serious complications of influenza. Good data exist documenting the impacts of early treatment on duration of illness and time off work, and on the occurrence of complications such as lower respiratory infections. Treating healthcare providers is feasible to implement, especially for inpatient care providers who can be provided drugs through the occupational health clinic. It also would be acceptable to the public, who would recognize the importance of maintaining quality healthcare and would understand that persons with direct patient contact are putting themselves at increased risk.

#### d) Population size

There are about 12.6 million persons designated as healthcare workers by the Bureau of Labor Statistics and about 820,000 EMS providers. Among HCWs, two-thirds are estimated to provide direct patient care services.

#### e) Unresolved issues

Further work is needed to hone definitions and estimate population sizes. Implementation issues include the approach to identifying healthcare providers who would be eligible for treatment and where the treatment would be provided, particularly for outpatient care providers.

### 3. Outpatients at highest risk for severe morbidity or mortality from influenza infection

#### a) Definition

The Advisory Committee on Immunization Practices defines groups at high risk (or increased risk) of complications from influenza infection during annual outbreaks based on age (6-23 months and >65 years) and underlying illnesses. Among this population of about 88 million persons, some can be identified who are at highest risk of severe disease and death. These include persons with hematopoietic stem cell transplants (HSCT) and solid organ transplants; those with severe immunosuppression due to cancer therapy or hematological malignancy; persons receiving immunosuppressive therapy for other illnesses (e.g., rheumatoid arthritis); persons with HIV infection and a CD4 count <200; persons on dialysis; and women who are in the second or third trimester of pregnancy.

#### b) Strategy

Treatment within 48 hours of symptom onset.

#### c) Rationale

Of the large group of persons who are at increased risk of severe disease or death from influenza, these groups represent the population at highest risk and who are least likely to be protected by vaccination. Studies show that neuraminidase inhibitor therapy decreases complications and hospitalizations from influenza in high-risk persons and one unpublished study shows a significant decrease in mortality among patients who have undergone a hematopoietic stem cell transplant.

#### d) Population size

About 150,000 persons have had an HSCT or solid organ transplant. Assuming that the period of severe immunosuppression after a cancer diagnosis lasts for 1 year, the population targeted with non-skin, non-prostate cancers would equal the incidence of about 1.35 million persons. Based on a birth cohort of 4.1 million, a 28-week risk period during the second and third trimesters, and an 8-week pandemic outbreak in a community, there would be about 400,000 pregnant women included in this risk group. Further work is needed to estimate the size of other immunosuppressed groups.

#### e) Unresolved issues

Specific definition of included groups and population sizes.

#### 4. Pandemic health responders, public safety workers, and key government decision-makers

##### a) Definition

Public health responders include those who manufacture vaccine and antiviral drugs; persons working at health departments who are not included as healthcare workers; and those who would be involved in implementing pandemic vaccination or other response components. Public safety workers include police, fire, and corrections personnel. Key government decision-makers include chief executives at federal, state, and local levels.

##### b) Strategy

Treatment within 48 hours of symptom onset.

##### c) Rationale

Preventing adverse health outcomes and social and economic impacts in a pandemic depend on the ability to implement an effective pandemic response. Early treatment of pandemic responders will minimize absenteeism and ensure that vaccination and other critical response activities can be maintained. Implementing early treatment for public health workers and vaccine manufacturers is feasible at workplace settings. Public safety workers prevent intentional and unintentional injuries and death, are critical to maintaining social functioning, and will contribute to a pandemic response, for example by ensuring order at vaccination clinics. A small number of decision-makers at federal, state, and local levels are needed to for an effective pandemic response.

##### d) Population size

An estimated 40,000 workers who produce pandemic vaccine and antiviral drugs in the U.S.; ~300,000 public health workers who would not be included in the HCW category; 3 million public safety workers; and a small number of government decision-makers.

##### e) Unresolved issues

Need to define the exact composition and size of this group.

#### 5. Outpatients at increased risk of severe morbidity or mortality from influenza

##### a) Definition

For planning purposes, this group would include those currently designated as high-risk groups, except for those who have been categorized as being at highest-risk and included in a separate category. This increased-risk group includes persons 6-23 months and >65 years old, or who have underlying illnesses defined by the ACIP as associated with increased risk. Definition of this group may change based on the epidemiology of the pandemic.

##### b) Strategy

Treatment within 48 hours of symptom onset.

#### c) Rationale

Early treatment has been shown to significantly decrease lower respiratory infections and to reduce the rate of hospitalization in elderly and high-risk populations. By extrapolation and based on the results of one small uncontrolled study, significant reductions of mortality can be expected as well. As these risk groups are familiar to the public given recommendations for annual vaccination, communication would be easy and acceptability high.

#### d) Population size

About 85.5 million persons are included in this group. Although all are at increased risk of annual influenza compared with the healthy under-65 year old population, there are different levels of increased risk for severe complications and death within this category. Further stratification may be possible based on several parameters including number of underlying conditions; recent hospitalization for a high-risk condition, pneumonia, or influenza; and age.

#### e) Unresolved issues

Stratifying this group into those at greater and lesser risk may be important if antiviral supplies are limited. Implementing treatment will be challenging given that it should be provided at the initial point of care to accrue the greatest benefit from early therapy.

### 6. Outbreak control

#### a) Definition

Use of antiviral drugs to support public health interventions in closed settings where an outbreak of pandemic influenza is occurring.

#### b) Strategy

Treatment of cases and post-exposure prophylaxis of contacts (once daily antiviral medication for 10 days).

#### c) Rationale

Influenza outbreaks in nursing homes are associated with substantial mortality and morbidity. Nursing home residents also are less likely to respond to vaccination. Post-exposure prophylaxis has been shown to be effective in stopping influenza outbreaks in closed settings.

#### d) Population size

The number of outbreaks that may occur during a pandemic is unclear. Measures should be implemented to prevent outbreaks including limiting visitors, vaccination of staff, furloughing non-critical staff, and screening and exclusion for illnesses consistent with influenza.

e) **Unresolved issues**

Should this policy also be implemented in prisons or other settings where explosive spread of illness may occur but the risk for severe complications is not high?

**7. Healthcare workers in ER, ICU, EMS, and dialysis settings**

a) **Definition**

Includes all staff in these settings who are required for effective functioning of these health care units.

b) **Strategy**

Prophylaxis

c) **Rationale**

Optimally effective functioning of these units is particularly critical to reducing the health impacts of a pandemic. Prophylaxis will minimize absenteeism in these critical settings.

d) **Population size**

Need to obtain population estimates.

e) **Unresolved issues**

Population sizes

**8. Pandemic societal responders and healthcare workers who have no direct patient contact**

a) **Definition**

This group includes persons who provide services that must be sustained at a sufficient level during a pandemic to maintain public well-being, health, and safety. Included are workers at healthcare facilities who have no direct patient contact but are important for the operation of those facilities; utility (electricity, gas, water), waste management, mortuary, and some transport workers.

b) **Strategy**

Treatment within 48 hours of symptom onset.

c) **Rationale**

Maintaining certain key functions is important to preserve life and decrease societal disruption. Heat, clean water, waste disposal, and corpse management all contribute to public health. Ensuring functional transportation systems also protects health by making it possible for people to access medical care and by transporting food and other essential goods to where they are needed.

d) **Population size**

Within these broad categories, there are about 2 million workers at healthcare facilities who have no direct patient contact; 730,000 utility workers; 320,000 waste management workers; 62,000 in mortuary services; and 2.3 million in transportation. Not all occupations within these categories would be classified as pandemic societal responders. Estimates are that 35% of this population will develop illness and present within 48 hours of onset regardless of pandemic severity.





#### e) Unresolved issues

Need to stratify within these groups to identify who fills specific pandemic societal response functions and to assess whether those functions could still operate if a substantial proportion of the workforce became ill during a 6-8 week pandemic outbreak within a community. Implementation issues need to be addressed, especially with respect to how persons would be identified as falling within this priority group when presenting for treatment and where that treatment would be provided.

### 9. Other outpatients

#### a) Definition

Includes persons not in one of the earlier priority groups.

#### b) Strategy

Treatment within 48 hours of illness onset.

#### c) Rationale

Treatment reduces the risk of complications and mortality, reduces duration of illness and shortens time off work, and decreases viral shedding and transmission. If sufficient antiviral supplies are available, providing treatment to all who are ill achieves equity and will be most acceptable to the public.

#### d) Population size

There are an estimated 180 million persons who are not included in previously targeted groups.

#### e) Unresolved issues

Consider whether there are any strata that can be defined within this population.

### C. Additional NVAC recommendations on antiviral drugs for pandemic influenza

In addition to recommendations for priority groups, NVAC unanimously adopted the following recommendations:

- Sufficient drugs should be stockpiled to address top priorities. NVAC recommends that the minimum stockpile size be about 40 million courses, allowing coverage of the top 7 priority groups.
- Oseltamivir should be the primary drug stockpiled, but some zanamivir also should be obtained as it is effective against some oseltamivir-resistant strains, may be preferred for treatment of pregnant women, and supporting two manufacturers enhances security against supply disruptions. Approximately 10% of the stockpile should be zanamivir if feasible and cost effective. No additional adamantanes should be stockpiled.
- Antiviral drugs can also be used as part of an international effort to contain an initial outbreak and prevent a pandemic. Use to slow disease spread early in a pandemic may be useful but requires large amounts of drug.
- Critical research should be conducted to support development and implementation of recommendations for pandemic influenza antiviral drug use, including:
  - Impact of treatment at hospital admission on outcome
  - Optimal treatment dose for H5N1 and other potential pandemic strains
  - Sensitivity and use of rapid diagnostic tests for H5N1 and other influenza strains with pandemic potential
  - Safety and pharmacokinetics of oseltamivir among infants <1 year old
  - Investigation of the impact of other drugs (new antiviral agents and other classes such as statins) on influenza
- Additional work with public and private sector groups should be done to further hone definitions of target groups and their estimated population sizes, and to provide further guidance on antiviral drug distribution and dispensing.





# appendix E: legal authorities

## Legal authorities

Numerous Federal and state statutes authorize relevant public health actions to address pandemic influenza. Knowledge of these authorities is essential for planning and implementing an effective response to an influenza pandemic.

Section 319(a) of the Public Health Service (PHS) Act (42 U.S.C. 247d), authorizes the HHS Secretary to declare a public health emergency and “take such action as may be appropriate to respond” to that emergency consistent with existing authorities. Appropriate action may include, as otherwise authorized, making grants, providing awards for expenses, entering into contracts, and conducting and supporting investigation into the cause, treatment, or prevention of the disease or disorder that presents the emergency. The Secretary’s declaration also can be the first step in authorizing emergency use of unapproved products or approved products for unapproved uses under section 564 of the Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3), or waiving certain regulatory requirements of the Department, such as select agents requirements, or—when the President also declares an emergency—waiving certain Medicare, Medicaid, and State Children’s Health Insurance Program (SCHIP) provisions. Under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 et seq.), the Federal Emergency Management Agency (FEMA), Department of Homeland Security, is authorized to coordinate the activities of Federal agencies in response to a Presidential declaration of a major disaster or emergency, with HHS having the lead for health and medical services. The President may also declare an emergency under the National Emergencies Act (50 U.S.C. 1601 et seq.)

The PHS Act provides additional authorities for core activities of HHS that will be needed to plan and implement an emergency response. For example, Sections 301, 319F-1, 402, and 405 of the PHS Act authorize the HHS Secretary to conduct and support research. Section 351 of the PHS Act and provisions of the Federal Food, Drug, and Cosmetics Act authorize the Secretary and the FDA to regulate vaccine development and production. Infrastructure support for preventive health services such as immunization activities, including vaccine purchase assistance, is provided under section 317 of the PHS Act. Section 319F-2 of the PHS Act authorizes the Secretary, in coordination with the Secretary of Homeland Security, to maintain the Strategic National Stockpile.



Section 361 authorizes the Secretary to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States, or from one state or possession into any other State or possession. CDC administers these regulations as they relate to quarantine of humans. Diseases for which individuals may be quarantined are specified by Executive Order; the most recent change to the list of quarantinable diseases was the April 1, 2005 Executive Order 13375, which amended the Executive Order 13295 by adding "influenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause, a pandemic" to the list. Other provisions in Title III of the PHS Act permit HHS to establish quarantine stations, provide care and treatment for persons under quarantine, and provide for quarantine enforcement. Section 311 of the PHS Act provides for Federal-state cooperative activities to enforce quarantine and plan and carry out public health activities. Section 311 also authorizes the Secretary to make available the resources of the PHS to help control epidemics and deal with other public health emergencies. HHS may also engage in certain international activities under section 307 of the PHS Act. Statute 42 U.S.C. § 97, which provides that the Secretary of Health and Human Services may request that Customs, Coast Guard, and military officers aid in the execution of quarantines imposed by states. The Secretary also has the authority to implement disease control measures in Indian country, if necessary. (25 U.S.C. 198, 231; 42 U.S.C. 2001). Indian Tribes, like states, are sovereign entities with police power authority to enact their own disease control rules and regulations. Tribal law should be consulted as well.

Further, HHS has broad authority to coordinate vaccine development, distribution, and use activities under section 2102 of the PHS Act, describing the functions of the National Vaccine Program. The Secretary has authority for health information and promotion activities under Title XVII and other sections of the PHS Act. HHS can provide support to states and localities for emergency health planning under Title III of the PHS Act.

Both Federal and state statutes may apply to specific interventions that would be implemented to control a pandemic. Key issues and relevant Federal authority are shown in Table E-1. States should review their authorities to respond to a public health emergency and to take necessary actions for its control.

**Table E-1. Key Pandemic Response Components and Legal Authorities.**

| Issue                                                                                              | Authority                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|----------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>Public sector vaccine or antiviral drug purchase</li> </ul> | <ul style="list-style-type: none"> <li>Antivirals have been added to the Strategic National Stockpile.</li> <li>At the time of a pandemic, the Federal Government could consider purchasing vaccine or antiviral drugs, if available.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <ul style="list-style-type: none"> <li>Indemnification of manufacturers</li> </ul>                 | <ul style="list-style-type: none"> <li>Executive Order 10789, as amended by Executive Order 13232, extends authorities under P.L. 85-804 to HHS to use indemnification provisions of the Federal Acquisition Regulations, 48 C.F.R. 50.403, if the contractor performs an activity that involves unusually hazardous risks and insurance is not available or sufficient to cover those risks. A contracting officer must review a request for indemnification, and the Secretary must personally approve the request and in some cases consult with Department of Homeland Security and the Office of Management and Budget.</li> <li>Other relevant, but more limited, indemnification authorities such as section 301(a)(7) of the PHS Act may also be available.</li> </ul> |

Table E-1. Continued

| Issue                                                                                                                     | Authority                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|---------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>■ Distribution of vaccines or antiviral drugs and liability protections</li> </ul> | <ul style="list-style-type: none"> <li>■ The Federal Government may mobilize the PHS Commissioned Corps to distribute vaccines or medications to Federal agencies with direct patient care responsibilities, or to states, tribes, and other localities through the National Disaster Medical System and through agreements between the Federal government, states, and localities. Provision of the medication by particular health care providers is a matter of state law.</li> <li>■ If a Federal employee administers an antiviral medication or vaccine in the course of his/her official duties, the employee is covered under section 224 of the PHS Act, which makes the Federal Tort Claims Act the exclusive remedy.</li> <li>■ If the provider were a Federal contractor generally, the contractor would be expected to carry malpractice insurance; expenses of purchasing such insurance generally are an allowable cost of the contract.</li> <li>■ State employees may be covered for malpractice or tort claims coverage under state law. States should consult their laws on this matter.</li> <li>■ Private sector employees would generally carry private malpractice insurance. They may also be covered by the Volunteer Protection Act, State Good Samaritan Act, or State Emergency compact provisions.</li> </ul> |
| <ul style="list-style-type: none"> <li>■ Compensation for persons injured by vaccine or antiviral medications</li> </ul>  | <ul style="list-style-type: none"> <li>■ If a person is injured following administration of a vaccine or antiviral medication, in connection with his/her employment, compensation may be available under a state's worker's compensation program. For Federal employees, compensation may be available under the Federal Employees' Compensation Act.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <ul style="list-style-type: none"> <li>■ Measures to decrease the transmission of infection</li> </ul>                    | <ul style="list-style-type: none"> <li>■ Individuals may be denied admission to the U.S. if thought to have a communicable disease of public health significance, as defined in CDC regulations. Individuals also may be isolated or quarantined by the Federal Government, or restricted from moving within or between states, if thought to have been exposed to or to be a source of infections to others of a communicable disease listed in an executive order signed by the President.</li> <li>■ State governors generally may restrict travel within their states and access to their states. Individual state law should be consulted to determine permissible exercise of this authority.</li> <li>■ States also may impose quarantine. The Secretary may aid states and localities in enforcement of their quarantine actions and accept state and local assistance in enforcing Federal quarantine.</li> <li>■ In settings such as long-term care facilities where there are public health risks associated with spread of a pandemic strain, states also may be able to compel an individual to take antiviral prophylaxis or be vaccinated, as circumstances warrant. State law should be consulted.</li> </ul>                                                                                                              |



## appendix F: current HHS activities

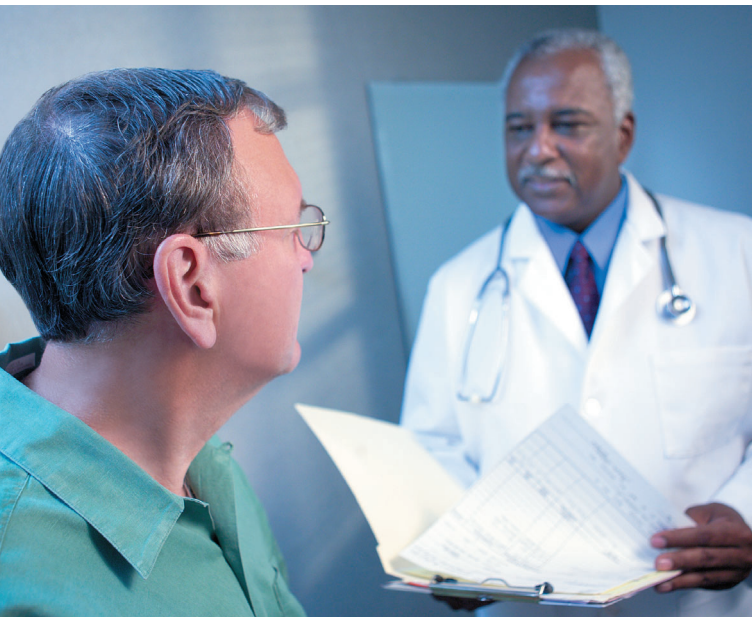
HHS is engaged in a broad array of activities to prepare for an influenza pandemic, although substantial work remains to be done to achieve the capabilities projected in this plan. Ongoing preparedness activities are summarized below.

### Planning and Coordination

**State and local planning.** During the past several years, HHS has provided financial assistance to states to enhance their emergency preparedness activities, including pandemic influenza, through cooperative agreements. CDC provides preparedness funding annually to the public health departments of all the states, certain major metropolitan areas, and other eligible entities through cooperative agreements. HRSA, in conjunction with CDC, awards complementary cooperative agreements to provide preparedness funding annually to the same set of awardees for investment primarily in hospitals and other healthcare entities.

**Part 2, Public Health Guidance for State and Local Partners,** provides HHS' state partners with guidance, in the form of 11 supplements that provide information they can consider in refining and updating their plans concurrent with the release of the HHS Pandemic Influenza Strategic Plan. A major objective will be to achieve interoperability with the federal government plan and thus compliance with the principles and procedures of the National Response Plan. In particular, HHS will encourage states and municipalities to conduct drills and exercises with which to assess their readiness to respond to an influenza pandemic. HHS will assist federal, state, and local decision-makers in understanding the contents of the Plan. HHS will also work with national associations, such as the Association of State and Territorial Health Officials (ASTHO), to assist in determining their roles and responsibilities.

**International collaborations.** Sustained human-to-human transmission anywhere in the world will be the triggering event to initiate a pandemic response by the U.S. Because we live in a global community, a human outbreak anywhere means risk everywhere. The U.S. will pursue a containment strategy, where feasible, acting in concert with WHO and other nations as appropriate.



*During the past several years, HHS has provided financial assistance to states to enhance their emergency preparedness activities, including pandemic influenza.*



*Sustained human-to-human transmission anywhere in the world will be the triggering event to initiate a pandemic response by the U.S. Because we live in a global community, a human outbreak anywhere means risk everywhere. The U.S. will pursue a containment strategy, where feasible, acting in concert with WHO and other nations as appropriate.*

HHS and the Department of State, Agency for International Development (USAID), the Department of Agriculture (USDA), and other agencies are developing a comprehensive international strategy on avian influenza and pandemic influenza. For example, HHS participates in ongoing global influenza surveillance through the CDC's WHO Collaborating Centers for Influenza. During the current pandemic alert, under the leadership of WHO, surveillance activities have been intensified and include strengthening national influenza center laboratories, training public health personnel, providing diagnostic reagents and other material support, and testing novel virus isolates from humans and animals. HHS has also contributed expertise to the WHO's influenza program and to WHO-led investigations of human cases of avian influenza in Asia. WHO has received additional funding by HHS to strengthen its Global Outbreak and Response Network (GOARN) to assist in surveillance and response worldwide and to establish a fund to ensure that laboratory specimens are shipped in a timely way to reference laboratories for further diagnostic work and confirmation.

As the pandemic threat continues, the U.S. will provide ongoing collaboration and assistance as part of the international response. During a pandemic, under the leadership of the HHS Office of Global Health Affairs (OGHA), the HHS Office of Public Health Emergency Preparedness (OPHEP), and the CDC, expertise and assistance will be provided for a coordinated international response. The U.S. is strengthening capacities in the currently affected region of East Asia and enhancing the ability of affected and high-risk countries to address the threat posed by H5N1 avian influenza. Currently, a number of bilateral and multilateral projects are underway in Asian countries to strengthen surveillance and laboratory capacity, develop rapid response capability, develop best practices for clinical case management of those infected, and develop vaccine production capability. In addition, the U.S. is working with the WHO to support international risk communication activities.

The newly formed International Partnership on Avian and Pandemic Influenza, announced by President Bush at the United Nations General Assembly on September 14, 2005, was created to improve international surveillance, transparency, timeliness, and response capabilities. Over 200 delegates from 88 countries and nine international organizations attended the first Senior Officials meeting on October 7, 2005. This initiative will strive for complete transparency, rapid response capabilities, and cooperative surveillance, and will facilitate the sharing of epidemiological data and samples among nations and with the World Health Organization (see Appendix H).



## Surveillance, Investigation, and Protective Public Health Measures

**Surveillance and epidemiological response.** Global collaboration, facilitated by the WHO Secretariat, is a key feature of influenza surveillance. The WHO established an international laboratory-based surveillance network for influenza in 1948, which currently consists of 112 National Influenza Center (NIC) laboratories in 83 countries, and 4 WHO Collaborating Centers for Reference and Research of Influenza (one is located at CDC). The primary purpose of this surveillance network is to detect the emergence and spread of new antigenic variants of influenza, use this information to update the formulation of influenza vaccine, and provide as much warning as possible about the next pandemic. This system provides the foundation of worldwide influenza prevention and control.

The WHO Collaborating Center located at CDC annually produces and distributes worldwide the WHO influenza reagent kits needed to identify the influenza viruses that are expected to circulate. This center also conducts comparative serologic and molecular studies of representative and unusual influenza viruses sent from NIC laboratories around the world.

*The newly formed International Partnership on Avian and Pandemic Influenza, announced by President Bush at the United Nations General Assembly on September 14, 2005, was created to improve international surveillance, transparency, timeliness, and response capabilities.*

The current HHS surveillance strategy expands the geographic coverage of sentinel disease reporting sites and seeks to improve the timeliness of reporting to public health officials. Clinical and epidemiological assessment tools and investigation strategies are being developed to help guide treatment and assess risk, respectively. Finally, HHS is working to ensure real-time outbreak identification for both domestic and international events. (More information is available at [www.cdc.gov/mmwr/preview/mmwrhtml/su5301a13.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/su5301a13.htm)).

**Diagnostics and detection.** Diagnostic testing for pandemic influenza virus may involve a range of laboratory assays, including rapid antigen tests, reverse-transcription polymerase chain reaction (RT-PCR), virus isolation, and immunofluorescence antibody (IFA) assays. Currently available rapid antigen detection tests are not sufficiently sensitive to reliably distinguish influenza subtypes. In addition, capacity for molecular detection of H5N1, and other strains with pandemic potential, is available at CDC and state reference labs, but is not widely distributed. Capability for production, validation, and distribution of reagents for inclusion in WHO reference typing kits is severely limited.

HHS has augmented state and local laboratory capacity to respond to anticipated surges in laboratory needs by establishing the Laboratory Response Network (LRN). The LRN has trained laboratory personnel in the detection and characterization of novel influenza strains and will work with health departments to provide surge capacity processing and test clinical specimens from patients who meet the case definition of pandemic influenza. Health departments and LRN laboratories will also provide guidelines to clinical laboratories for the safe handling, processing, and testing of specimens. Local public health departments with laboratories not part of LRN or clinical laboratories should contact their state health department for more information regarding laboratory guidelines.

**Infection control.** On its website, CDC provides guidance to healthcare and public health partners on infection control measures designed to limit the spread of pandemic influenza. Guidance is included on the selection and use of personal protective equipment, such as masks, gloves, and gowns; hand hygiene and safe work practices; cleaning and disinfection of environmental surfaces; handling of laboratory specimens; and post-mortem care. The guidance also covers infection control practices related to the management of infectious patients, the protection of persons at high risk for severe influenza or its complications, personal protection in homes and in communities, and issues concerning occupational health.

CDC recommendations also outline actions that may be taken during the earliest stage of a pandemic when the first potential cases or disease clusters are detected. In this setting, individual-level containment measures (e.g., patient isolation and identification, monitoring, quarantine of contacts) may be useful in slowing the spread of pandemic influenza.



The overall HHS strategy includes a comprehensive approach to protect travelers and decrease entry of pandemic influenza into the United States. This includes: 1) issuing travel advisories and providing education to travelers to decrease their risk of acquiring pandemic influenza infection; 2) identifying persons with influenza-like illness during transit and implementing protocols to limit potential transmission to other passengers; 3) implementing point-of-entry interventions to rapidly identify persons who may have pandemic influenza; 4) isolating persons and identifying and quarantining contacts using fixed quarantine stations and other sheltering models; and 5) attempting to prevent exportation of illness from the United States to other countries and encouraging affected countries to implement similar exit screening.

HHS public health research priorities include evaluating the extent to which infection control measures, such as social distancing, mask use, and hand hygiene, prevent or minimize the spread of pandemic influenza within healthcare settings. Related to these priorities, the study of the relative clinical importance of the various modes of transmission is necessary to better define scientific rationale for various types of personal protective equipment.

## Vaccines and Antivirals

**Influenza vaccine.** Currently, influenza vaccine for the annual, seasonal influenza program comes from four manufacturers. However, only a single manufacturer produces the annual vaccine entirely within the U.S. Thus, if a pandemic occurred and existing U.S.-based influenza vaccine manufacturing capacity was completely diverted to producing a pandemic vaccine, supply would be severely limited. Moreover, because the annual influenza manufacturing process takes place during most of the year, the time and capacity to produce vaccine against potential pandemic viruses for a stockpile, while continuing annual influenza vaccine production, is limited. Since supply will be limited, it is critical for HHS to be able to direct vaccine distribution in accordance with predefined groups (see Appendix D); HHS will ensure the building of capacity and will engage states in a discussion about the purchase and distribution of pandemic influenza vaccine.

**Vaccine production capacity:** The protective immune response generated by current influenza vaccines is largely based on viral hemagglutinin (HA) and neuraminidase (NA) antigens in the vaccine. As a consequence, the basis of influenza vaccine manufacturing is growing massive quantities of virus in order to have sufficient amounts of these protein antigens to stimulate immune responses. Influenza vaccines used in the United States and



*The overall HHS strategy includes a comprehensive approach to protect travelers and decrease entry of pandemic influenza into the United States.*



*HHS is currently supporting a number of vaccine manufacturers in the advanced development of cell-based influenza vaccines with the goal of developing U.S.-licensed cell-based influenza vaccines produced in the United States.*

around world are manufactured by growing virus in fertilized hen's eggs, a commercial process that has been in place for decades. To achieve current vaccine production targets millions of 11-day old fertilized eggs must be available every day of production.

In the near term, further expansion of these systems will provide additional capacity for the U.S.-based production of both seasonal and pandemic vaccines, however, the surge capacity that will be needed for a pandemic response cannot be met by egg-based vaccine production alone, as it is impractical to develop a system that depends hundreds of millions of 11-day old specialized eggs on a standby basis. In addition, because a pandemic could result from an avian influenza strain that is lethal to chickens, it is impossible to ensure that eggs will be available to produce vaccine when needed.

In contrast, cell culture manufacturing technology can be applied to influenza vaccines as they are with most viral vaccines (e.g., polio vaccine, measles-mumps-rubella vaccine, chickenpox vaccine). In this system, viruses are grown in closed systems such as bioreactors containing large number of cells in growth media rather than eggs. The surge capacity afforded by cell-based technology is insensitive to seasons and can be adjusted to vaccine demand, as capacity can be increased or decreased by the number of bioreactors or the volume used within a bioreactor. In addition to supporting basic research on cell-based influenza vaccine development, HHS is currently supporting a number of vaccine manufacturers in the advanced development of cell-based influenza vaccines with the goal of developing U.S.-licensed cell-based influenza vaccines produced in the United States.

*Dose-sparing technologies.* Current U.S.-licensed vaccines stimulate an immune response based on the quantity of HA (hemagglutinin) antigen included in the dose. Methods to stimulate a strong immune response using less HA antigen are being studied in H5N1 and H9N2 vaccine trials. These include changing the mode of delivery from intramuscular to intradermal and the addition of immune-enhancing adjuvant to the vaccine formulation. Additionally, HHS is soliciting contract proposals from manufacturers of vaccines, adjuvants, and medical devices for the development and licensure of influenza vaccines that will provide dose-sparing alternative strategies.

**Antiviral drugs.** One of currently circulating H5N1 virus strains is resistant to one of two existing classes of antiviral drugs. Only the neuraminidase inhibitors, oseltamivir (Tamiflu®) and zanamivir (Relenza®) provide clinical benefit against all of the H5N1 virus strains currently circulating in Asia. As of October 2005, the Strategic National Stockpile includes 2.3 million treatment courses of oseltamivir (Tamiflu®) and 84,000 treatment courses of zanamivir (Relenza®). The Strategic National Stockpile is expecting delivery on an additional 2 million courses of Tamiflu by the end of 2005. HHS is committed to acquiring additional courses of these drugs, as stated earlier, and increasing U.S.-based antiviral production.

**Further research and development.** HHS plans to accelerate basic discovery in priority areas such as natural history of influenza progression, animal-to-human transmission of disease, and virus/host interaction. It plans to do this by supporting academic and private-sector research grants in priority areas that could contribute to the generation of new vaccines, drugs, and diagnostics and expanding support for multidisciplinary focus in priority areas.

HHS also plans to accelerate development of vaccines, drugs, and diagnostics by 1) supporting and accelerating the clinical testing of candidate products that are in advanced states of development (e.g. recombinant influenza vaccine and new and/or long-acting neuraminidase inhibitor antiviral drugs); 2) supporting evaluation and licensure efforts for injectable and pediatric formulations of currently licensed drugs, of new antiviral drugs, 3) supporting accelerated preclinical development including in vitro and animal model studies of promising countermeasures (e.g. siRNA and common-epitope vaccines, new immune-stimulating adjuvants, novel antiviral drugs, and genomic/proteomic microchip approaches to rapid diagnostics using surrogate markers of early infection). These will be accomplished using milestone-driven grants with private-sector partners and public/private sector collaborations; 4) supporting revised protocols and increased resources to reduce the time to prepare and qualify influenza virus reference strains used in vaccine manufacturing and to calibrate HA content in influenza vaccines for potency assays; and 5) developing accurate, rapid point-of-care diagnostic tests for clinical use during a pandemic, which will require additional investment in new technology leading both to better diagnosis of influenza and differentiation among the various respiratory infections.

## Healthcare and Emergency Response

**Clinical care.** HHS is working with the medical community to establish clinical procedures for the initial screening, assessment, and management of patients with suspected novel influenza during a pandemic. Early recognition of illness caused by a novel influenza virus strain will rely on a combination of clinical and epidemiological features. Guidelines for the management of influenza-related complications, including community-acquired pneumonia, have also been developed.

**Healthcare surge capacity.** An influenza pandemic may increase the demand for hospital inpatient and intensive care unit (ICU) beds and assisted ventilation services by more than 25%. HHS is developing a deployable mass casualty capability that could be used to supplement hospitals. HHS recommends that hospitals develop their own response plans. **Supplement 3** provides guidance to hospitals on several components of a plan including hospital surveillance, hospital communication, staff education and training, triage and admission procedures, staffing and bed capacity, consumable and durable supplies, and planning for provision of care in non-hospital settings.

**Psychosocial support services.** HHS is focusing on the institutionalization of psychosocial support services that will help healthcare workers manage emotional stress during the response to an influenza pandemic and resolve related personal, professional, and family issues. HHS is also addressing the preparation of informational materials for employees and their families and the development of workforce resilience programs to assist families of deployed workers.

**Mass fatalities and mortuary services.** HHS understands that the timely, safe, and respectful disposition of the deceased is an essential component of an effective response. Pandemic influenza may quickly rise to the level of a catastrophic incident that results in mass fatalities, which will place extraordinary demands (including religious, cultural, and emotional burdens) on local jurisdictions and the families of the victims. A catastrophic incident involving mass fatalities will require federal assistance to transport, process, and store deceased victims and support final disposition and personal effects processing. Most local jurisdictions will be severely strained to handle mass fatalities or may experience profound difficulties.

If local and state fatality management capacities are exceeded, HHS, under ESF #8, will coordinate with the Department of Homeland Security (DHS) and the Department of Defense (DoD) to assist in providing mortuary services; establishing temporary morgue facilities; and processing, preparation, and disposition of human remains.

*An influenza pandemic may increase the demand for hospital inpatient and intensive care unit (ICU) beds and assisted ventilation services by more than 25%. HHS is developing a deployable mass casualty capability that could be used to supplement hospitals.*



## Communications and Outreach

**Risk communication.** HHS is the federal government's lead agency in pandemic influenza communications. An HHS Communications and Public Outreach Strategy for Pandemic Influenza has been developed. This strategy is designed to prepare U.S. citizens and communities for a pandemic; communicate the need for local preparedness and an understanding of the implications of a pandemic; and develop consistent, clear, honest messages and materials that can be shared broadly in the U.S. and with global partners. Components of the strategy include 1) assessment of current public (or community) knowledge through ongoing surveillance of media and surveys of the public and providers; 2) development of materials such as message maps that have been developed and tested in focus groups; 3) formative audience research; 4) cross-government communication coordination; 5) facilitating community and business continuity planning by helping these sectors communicate with their constituents and prepare; 6) public engagement through forums and stakeholder meetings on such important policy issues as allocation of limited drugs and vaccines; 7) web communications development through a consolidated, centralized U.S. government website; 8) international outreach to support our global partners, in cooperation with the WHO Secretariat; and 9) continuing efforts to raise awareness about the importance of seasonal influenza vaccine and to promote increased yearly compliance of influenza and pneumococcal vaccination.

A Public Engagement Pilot Project on Pandemic Influenza was initiated in July 2005 to discuss goals for a pandemic influenza vaccination program and to pilot test a new model for engaging citizens on vaccine related policy decisions. The pilot project was sponsored by interested organizations including the Atlanta Journal Constitution, the Lounsbery Foundation, the Keystone Center, the Institute of Medicine, the University of Georgia, the CDC's National Immunization Program, the HHS National Vaccine Program Office, and the Study Circles Resource Center. To conduct this public consultation, the sponsors made use of an innovative model for engaging stakeholders from various organizations with an interest in pandemic influenza, and individual citizens-at-large from the 4 principal regions of the United States. The anticipated major benefits from this public consultation were the development of an improved plan to combat pandemic influenza and one more likely to gain public support, and a demonstration that citizens can be productively engaged in informing vaccine-related policy decisions. A complete assessment of the potential benefits from this pilot project is still underway and important potential outcomes such as improved relationships and increased trust among the participants have not been yet been measured.



*HHS understands that the timely, safe, and respectful disposition of the deceased is an essential component of an effective response.*



# appendix G

## TABLE OF CONTENTS

|                                                                         |           |
|-------------------------------------------------------------------------|-----------|
| <b>I. Introduction .....</b>                                            | <b>43</b> |
| A. Critical basic research foundation.....                              | 44        |
| B. The transition to applied research.....                              | 45        |
| <b>II. U.S. pandemic influenza: Research activities and needs .....</b> | <b>47</b> |
| A. Basic virology and molecular biology.....                            | 47        |
| B. Animal surveillance .....                                            | 48        |
| C. Human surveillance and epidemiology .....                            | 50        |
| D. Immune response parameters.....                                      | 52        |
| E. Diagnostic development.....                                          | 53        |
| F. Antiviral drug development.....                                      | 54        |
| G. Vaccine development .....                                            | 55        |
| H. Research resources and training.....                                 | 57        |
| I. Research priorities during a pandemic.....                           | 57        |
| J. Research priorities after a pandemic.....                            | 58        |

## I. INTRODUCTION

Influenza is not a disease that can be eradicated. Wild birds and domestic animals harbor influenza A viruses, which have the potential for direct transmission to man and for genetic recombination with human influenza A strains. As a result, animal reservoirs present opportunities for the emergence of influenza A viruses that are antigenically novel to the human immune system. The emergence of such a virus that develops the ability for person-to-person transmission could lead to an influenza pandemic. Although exactly when and where the next influenza pandemic will occur is unknown, it is possible that the outcome will vary from serious to catastrophic. Expanding research on influenza before the next pandemic occurs will promote a better understanding of influenza and will lead to new strategies and products that could improve the effectiveness of a pandemic response and prevent disease and death.

Research on influenza is conducted by several HHS and other U.S. government agencies such as the Department of Defense, Department of Veteran's Affairs, and the Department of Agriculture. The largest proportion of influenza research is supported by the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), primarily through investigator-initiated grants and contracts. These agreements support both basic and applied research on influenza virus biology, epidemiology, pathogenesis, and immunology, as well as the development of new and improved influenza diagnostics, antiviral drugs, and vaccines. Other influenza research is supported through the intramural program at NIH, including the Laboratory of Infectious Diseases (LID), which also has a strong focus in new vaccine development.

The Centers for Disease Control and Prevention (CDC), through the National Center for Infectious Diseases and the National Immunization Program, supports a broad intramural and collaborative influenza research portfolio including studies on influenza epidemiology, immunology, vaccines, and vaccination programs.

The Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER), conduct and/or advise on research on influenza vaccines and antivirals, respectively.

The Agency for Healthcare Research and Quality (AHRQ) supports research on surge capacity, the use of information systems for bed-tracking and syndromic surveillance in emergency departments, and primary care.

*Expanding research on influenza before the next pandemic occurs will promote a better understanding of influenza and will lead to new strategies and products that could improve the effectiveness of a pandemic response and prevent disease and death.*





*The intent of the NRP is to reduce America's vulnerability to terrorism, major disasters, and other emergencies; to minimize the damage resulting from these emergencies; and to facilitate recovery.*

In April 2005, the Institute of Medicine (IOM) convened The John R LaMontagne Memorial Symposium on Pandemic Influenza Research to address the current state of the research and outline future priorities of scientific research for pandemic influenza. HHS will consider these recommendations, as well as other outside expert opinion, as the basis for scientific research in influenza in the near future. The combined efforts of HHS agencies including NIH, CDC, and FDA, as well as the private sector, will be needed to develop and implement this research agenda.

Research has provided the underpinning of many of the tools HHS currently has to combat influenza and will be the basis of those that are developed in the future. This document will summarize critical HHS influenza research activities. As much of the research on influenza A is applicable to both interpandemic (H3N2 & H1N1) and pandemic influenza, this document will cover both.

## **A. Critical basic research foundation**

Basic research on influenza facilitates new ways of detecting and rapidly characterizing these viruses as they emerge. Most Federal funds currently available for influenza research are provided through NIH in the form of grant support for scientists to study fundamental issues related to basic biology, virology, immunology, pathogenesis, and the development of new diagnostics, antiviral agents, and vaccines. In addition, NIAID supports centralized research resources such as contracts to screen new drugs, develop new animal models, and establish a reagent repository. These resources are available to research scientists around the world and contribute to pandemic preparedness.

Basic research on the virus and its structure, the factors that contribute to its virulence, and its ability to evade the immune system, and an understanding of the genetic changes that permit an influenza virus to suddenly acquire the ability to transmit between species, provide important information for fighting pandemic influenza. The development of new systems for manipulating influenza genes to create strains (referred to as "reverse genetics") provides researchers with the opportunity to systematically uncover the function and interactions of each gene in the influenza virus genome. The application of this technology has already begun to expand understanding of virus-host range restriction, viral replication, and pathogenicity in order to speed the production of inactivated and live-viral vaccine candidates.

*Through NIH and private sector-supported applied research programs, new vaccine candidates are being developed and clinically tested.*

An increasing number of materials and reagents are being made available through the NIAID Influenza Reference Repository, the CDC WHO Collaborating Center, and FDA/CBER, including antibodies and reference antigens to a number of avian influenza viruses considered to be of high pandemic potential. Updating the reagents in this library and making them available to research scientists around the world remains an area of high priority.

## **B. The transition to applied research**

The plasticity of the influenza genome facilitates the virus's adaptability and its ability to escape the specific host immune responses, leading to the need for annual vaccination with updated vaccine. Through NIH and private sector-supported applied research programs, new vaccine candidates are being developed and clinically tested. One successful public-private partnership has been the government's long-standing involvement in the development of the live-attenuated influenza virus vaccine, which was licensed by the FDA in 2003.

Efforts are also underway to enhance the immunogenicity of inactivated influenza vaccines (especially for very young and very old individuals) by administering them using new delivery systems, providing them in higher doses, or by combining them with adjuvants or supplemental proteins. Vaccines that contain common protein epitopes from influenza viruses may provide generic protection against a wide range of influenza viruses and are being aggressively pursued. While the exact subtype of influenza virus that will cause the next pandemic is not known, producing prototypic vaccine reference strains that can be used in developing vaccine candidates is essential for preparedness and is being supported by the CDC, FDA, the NIH, and other international laboratories. Production and clinical testing of investigational lots of vaccines made with these reference strains should be supported as they become available.

In addition to vaccine-related research, the NIH supports several programs on the development of new antiviral agents against influenza. These programs range from target identification to the support of clinical trials. In vivo and in vitro screening programs to identify promising drug candidates provided by private sector companies and academic laboratories are also ongoing.

The NIAID Biodefense Partnership and Challenge Grant Programs provide support to private sector companies to develop new vaccines against influenza, including non-egg based vaccine platforms, new antiviral drugs against influenza, and genomics-based diagnostic assays against a number of acute respiratory viruses, including influenza.



Applied research also leads to the development of tools and to refinement of strategies that are critical to effective surveillance and pandemic response programs. Improved influenza rapid diagnostic tests, development of more sensitive and rapid laboratory assays for detecting and subtyping influenza viruses, and new high capacity methods to test influenza virus strains for susceptibility to antiviral drugs—and their implementation at CDC, public health, and hospital laboratories—all are key to identifying and tracking disease before and during a pandemic, and to providing public health and health care providers the information needed to make optimal decisions.

Another component of applied research relates to the AHRQ support for research on health system preparedness. This work has focused on the use of real-time information systems to track hospital bed capacity, including emergency department and ventilator beds. In addition, a mass prophylaxis and vaccination program is currently part of the Cities' Readiness Initiative and the Strategic National Stockpile training activities.

In addition, epidemiological, programmatic, and behavioral research results lead to new understanding of influenza infections including their consequences and who is at risk, strategies to improve vaccination delivery and help eliminate racial and ethnic disparities, and effective communications messages and tools that will be vital to a pandemic response.

This appendix identifies ongoing HHS research activities for influenza, as well as highlights future research priorities that will allow the U.S. to prepare, respond, and reduce the overall morbidity and mortality associated with pandemic influenza.

## II. U.S. PANDEMIC INFLUENZA: RESEARCH ACTIVITIES AND NEEDS

### A. Basic virology and molecular biology

Influenza viruses, members of the family Orthomyxoviridae, are classified into three types: A, B, and C, with influenza A causing the most severe disease in humans and the most likely to trigger a pandemic. While a number of structural proteins have been identified in influenza A viruses, the two surface proteins, the hemagglutinin (HA) and neuraminidase (NA), play key roles in the pathogenesis of the virus and the host's immune response. Although only two influenza A subtypes currently co-circulate globally in humans (H1N1 and H3N2), at least 16 distinct antigenic subtypes of HAs (H1 to H16) and nine NAs (N1 to N9) have been identified in wild aquatic birds. In spite of the severity of influenza disease, little is known about the role of the viral proteins in the virus' pathogenicity or transmission.

#### Goals:

- Understand the mechanism(s) by which influenza viruses of any novel subtype emerge in humans and animals.
- Identify genetic mutations that correlate with antiviral resistance.

#### Ongoing HHS activities:

- Conducting studies to examine the molecular biology and epidemiology of pathogenic viruses in avian reservoirs, with a focus on defining the molecular basis of virulence for avian viruses such as the 1997 and 2004–2005 H5N1 viruses and the role of virulence factors and pathogenic determinants in disease
- Using the Influenza Genome Sequencing Project to put influenza sequence data rapidly in the hands of scientists, enabling them to further study how influenza viruses evolve, spread, and cause disease
- Establishing libraries of antigenically and genetically characterized human and animal influenza viruses
- Developing new rapid methods to detect antiviral resistance in clinical influenza isolates
- Studying viral evasion mechanisms to the innate immune response mechanism, and how influenza A and B viruses modulate the innate defenses of the host
- Examining the molecular basis of transmission of influenza viruses among animals and humans

#### Future priorities:

- Determine the compatibility of gene segments derived from human and animal influenza viruses to reassort—an event that may result in the emergence and interspecies transmission of novel influenza viruses.
- Evaluate the role of mutations and constellations of mutations in antiviral drug resistance using a reverse genetics system to find viruses with specific mutations associated with drug resistant phenotypes.
- Examine the reason behind the high lethality of the 1918 influenza pandemic.
- Identify the pandemic influenza genes that have the greatest potential for interspecies transfer. Research the role of other viral proteins in the pathogenesis of influenza.



- Identify and characterize the intracellular trafficking of influenza virus proteins, nucleic acids and complexes in avian and mammalian systems.
- Research the structural diversity of sialosides expressed at the surface of airway epithelial cells in avian and mammalian species.
- Conduct comparative analysis of membrane fusion mechanisms by HA in avian and mammalian cells.
- Research interactions between HA and mucins from avian and mammalian airway.
- Optimize reverse genetic techniques to facilitate isolation of reassortant influenza viruses.
- Research the role of other viral proteins in the pathogenesis of influenza.
- Determine the molecular basis of virulence in humans and animals.
- Support studies on the evolution and emergence of influenza viruses, including the identification of factors that affect influenza host-range and virulence.

## B. Animal surveillance

Animal surveillance of influenza is important for several reasons. Previous epidemics of human infection with influenza in 1957 and 1968 were preceded by circulation of these viruses in animals. This was likely true in 1918 also, though the specific source is not clear. In addition, outbreaks in animals can be associated with considerable economic costs due to culling of infected animals and reduction in trade.

Recent outbreaks in domestic poultry in Asia associated with cases of human disease highlight the importance of coordinating surveillance activities. Surveillance for influenza A viruses in poultry in the U.S. has increased since the outbreak of highly pathogenic avian influenza (HPAI) in Pennsylvania and surrounding states in 1983 and 1984. Investigations may be conducted by state animal health officials, USDA-accredited veterinarians, university personnel, or members of the poultry industry. Samples from affected flocks are routinely submitted to state laboratories for diagnosis. If importation of HPAI is suspected, a Foreign Animal Disease Diagnostician will conduct an investigation and submit samples directly to the National Veterinary Services Laboratories (NVSL) in Ames, Iowa.



*Recent outbreaks in domestic poultry in Asia associated with cases of human disease highlight the importance of coordinating surveillance activities.*

Most birds submitted for entry into the United States must be quarantined in USDA-approved quarantine facilities. During quarantine, avian influenza virus isolation is attempted on samples collected from all dead birds and some live birds.

Surveillance in the U.S. for influenza A viruses in swine and horses is currently less systematic than in poultry. While no requirement exists for USDA notification when cases or outbreaks of influenza occur in these animals, considerable interest exists in understanding the viruses that are circulating among them. In general, only outbreaks in swine of unusual severity or duration are likely to be investigated and reported. On the other hand, surveillance for influenza viruses causing disease in horses has practical utility because data generated from analysis of equine influenza viruses can be used to guide equine influenza vaccine formulation.

**Goal:**

- Understand the prevalence, ecology, and spread of influenza virus subtypes in animal reservoirs.

**Ongoing HHS activities:**

- Conducting an ongoing animal influenza surveillance program in Hong Kong and other parts of Asia in wild birds, live bird markets, and pigs
- Conducting an annual surveillance of influenza viruses in wild migrating birds in North America and collaborating with the Canadian Wildlife Service to isolate influenza viruses from migratory birds

**In addition to the HHS activities, other agencies are also conducting animal research.**

- WHO has initiated limited systematic influenza surveillance in swine, and recent avian outbreaks caused by highly pathogenic influenza strains are likely to lead to new avian surveillance activities.
- The Office International des Epizooties (OIE) has established reference laboratories for avian and equine influenza. These laboratories provide diagnostic testing including virus characterization, reagents, and training. The OIE member countries report outbreaks of avian, equine, and swine influenza, and the OIE prepares a yearly summary of these reports.
- The Animal Health Trust, Newmarket, U.K., has taken the lead in organizing a program for equine influenza surveillance and reporting.
- The U.S. Department of Agriculture (USDA) conducts influenza surveillance in domestic animals.
- The USDA's Animal and Plant Health Inspection Service (APHIS) has been monitoring live bird markets in the northeastern region of the U.S. since 1986 for the presence of avian influenza viruses that may pose a threat to commercial poultry.

**Future priorities:**

- Expand surveillance of influenza viruses in poultry, swine, and wild migratory birds in the U.S. and abroad.
- Sequence known human and animal influenza viruses to understand their molecular evolution.

*Year-round influenza surveillance provides information on the baseline level of influenza activity during the summer, and these data have the potential to become an important component of early detection for a pandemic.*

### C. Human surveillance and epidemiology

The information regarding circulating influenza strains is used to monitor global influenza activity and to update the formulation of annual influenza vaccines. It is also used to detect novel influenza strains (i.e., influenza A subtypes that have not recently circulated among people) that infect humans, leading to the implementation of control measures and providing early warning of a possible pandemic.

CDC conducts and coordinates influenza surveillance in the United States. Surveillance focuses on collecting influenza viral isolates for testing, monitoring morbidity and mortality, and identifying unusual or severe influenza outbreaks (see Part 2, [Supplement 1](#)). The U.S. national influenza surveillance system includes: laboratory surveillance, outpatient influenza-like illness (ILI) surveillance, pneumonia and influenza (P&I) related mortality surveillance, and an assessment of influenza activity at the state level. Traditionally, U.S. influenza surveillance has been conducted from October through mid-May, but is now being conducted year-round. Year-round influenza surveillance provides information on the baseline level of influenza activity during the summer, and these data have the potential to become an important component of early detection for a pandemic.

#### Goals:

- Understand the prevalence of disease in select populations or other groups.
- Understand the factors involved in transmission of influenza.
- Understand the efficacy of potential control measures.

#### Ongoing HHS activities:

- Partnering with the WHO through the Global Outbreak Alert and Response Network (GOARN) to assure overall improvements in global disease detection and control
- Providing additional support and assistance to foreign governments for the development or improvement of influenza surveillance networks
- Providing support for BioSense: a state-of-the-art, multi-jurisdictional, data-sharing program to facilitate surveillance of unusual patterns or clusters of disease activity around the country
- Conducting surveillance of pediatric influenza-associated deaths, using the national reportable disease list by the Council of State and Territorial Epidemiologists, to aid in the identification of high-risk groups and in formulating improved immunization policies



- Conducting surveillance through the New Vaccine Surveillance Network to detect all influenza cases among children <5 years old who are admitted to a hospital to evaluate the effectiveness of influenza vaccination and the costs associated with pediatric influenza illness
- Supporting Emerging Infections Program network sites, which characterize the burden of severe, laboratory-confirmed pediatric influenza in the U.S.
- Supporting the Models of Infectious Disease Agent Study (MIDAS), which develops computational models that are agent-based, taking account of how individual people interact in their daily lives and examining how a pandemic might spread under various approaches to intervention
- Conducting studies to obtain annual estimates of vaccine effectiveness against laboratory-confirmed influenza illness that are underway
- Making interagency agreements with DoD for support of Naval Medical Research Unit [NAMRU] 2 (Jakarta) & 3 (Cairo) for surveillance of influenza and emerging infectious diseases
- Evaluating the role of children as vectors for the transmission of influenza infection within a community and the impact/use of vaccines to reduce spread and potentially alter the course of an epidemic

In addition, the World Health Organization (WHO) supports an international laboratory-based surveillance network for influenza to detect the emergence and spread of new antigenic variants of influenza.

#### **Future priorities:**

- Conduct serological studies of humans who are in close contact with animal reservoirs to assess both cross-species transmission and subsequent human-to-human transmission.
- Determine population effects of vaccines by studying the impact of vaccination on annual influenza epidemics, developing models for predicting the impact of annual vaccination on a future pandemic, and establishing the cost savings of different vaccination programs.
- Determine the impact of antiviral drugs and increasing social distance measures in annual influenza epidemics, including studying the evolution of resistance and describing the behavior of individuals during an outbreak.
- Develop further analytical and computational models to study the potential impact of strategies to prevent emergence, contain spread, reduce mortality and morbidity, and make good use of limited resources. Models need to examine the individual and combined impact of intervention strategies.
- Establish a database of influenza subtypes, including sequences, clinical information, and temporal and geographic data.
- Examine the transmission of influenza viruses specifically in healthcare settings, evaluating the use of different personal protective equipment devices to prevent spread and the impact of vaccinating health care workers.

## D. Immune response parameters

Historical experience with influenza vaccines suggests that two doses of inactivated vaccine will be needed to induce adequate levels of immunity to a pandemic strain of influenza. Enhancing the immunogenicity of a pandemic vaccine so that a one dose course could be used could ultimately reduce the time and cost required to protect the population. This may require inclusion of an adjuvant—a substance included in vaccines to increase the strength of the immune response—in the formulation of a pandemic vaccine. Further investigation needs to be done to understand whether adjuvants will be useful in a pandemic situation.

### Goals:

- Determine how to further enhance the immunogenicity of influenza vaccines through adjuvants or alternative delivery approaches.
- Optimize immunological assays.
- Define serologic correlates of immunity.

### Ongoing HHS activities:

- Developing new adjuvants
- Identifying immunologic markers that might correlate to immunity
- Evaluating mechanisms of secondary infections after influenza infections
- Creating "Immune Modeling Centers" that simulate human innate immune responses to adjuvants or immune modulators
- Studying immune responses to influenza vaccination in special populations and defining the immune parameters responsible for vaccine failure/response

### Future priorities:

- Defining further the immunological markers (such as cell mediated immunity, cytokine production) that might constitute correlates of protection and determine the role of humoral, cellular, and mucosal immunity in protection against influenza disease, with an emphasis on those populations at highest risk
- Developing serological assays to assess immune responses to help researchers determine the immune mechanisms responsible for strong vs. weak immune responses to influenza vaccines
- Developing and evaluating new adjuvants
- Evaluating established and new immunotherapies on infections caused by novel influenza viruses
- Evaluating innate immune effector molecules (such as surfactants, mannose binding lectins, defensins, etc.) in the treatment of influenza
- Evaluating innate immune activation molecules (TLR 3,4,7,8,9 agonist, NOD receptors, etc.) in the treatment of influenza
- Developing modulators of inflammatory cascades



*Early detection of new influenza outbreaks is critical to limit the spread of infection and control its impact on human health.*

## E. Diagnostic tools development

Early detection of new influenza outbreaks is critical to limit the spread of infection and control its impact on human health. The influenza diagnostic tests that are currently available have limited sensitivity and specificity and are not able to discriminate between viral subtypes. Novel diagnostic tools are needed in the detection of newly emerging influenza strains and to discriminate between different influenza subtypes.

The ability to test new diagnostic technologies in public health laboratory settings is also being enhanced through the distribution of standardized protocols for lab methods by introducing new techniques, such as multiplex PCR, and by expanding the role for use of molecular techniques to rapidly diagnose respiratory agents, including influenza types and subtypes.

### Goal:

- To support the development of rapid and reliable diagnostic tests for the identification and characterization of epidemic and pandemic influenza viruses.

### Ongoing HHS activities:

- Developing new rapid antigen detection methods
- Developing subtype specific reference antisera for use in the rapid identification of novel influenza viruses
- Standardizing molecular techniques for the identification of influenza virus types and subtypes, including those normally circulating in human populations (H1, H3) and recent avian subtypes of interest (H5, H7 and H9)
- Developing a diagnostic microarray for influenza A (the "Flu Chip") that will provide information as to whether or not an individual is infected with influenza as well as provide both type and antigenic subtype characterization of the virus
- Developing new diagnostics that can discriminate between several different causes of respiratory diseases, including avian influenza and SARS
- Developing techniques for identifying host-response profiles for early pre-symptomatic infections

**Future priorities:**

- Develop more new technologies and platforms that allow for the detection and discrimination of newly emerging influenza virus subtypes.
- Develop new rapid antigen detection methods for use on clinical specimens obtained from patients infected with a novel influenza.
- Develop new rapid methods to detect antiviral resistance in clinical influenza isolate.
- Develop techniques for identifying host-response profiles for early detection of pre-symptomatic infections.

**F. Antiviral drug development**

In the event of a pandemic, antiviral drugs will be the first line of defense before a vaccine is available and could delay the spread of the pandemic, particularly if the strain is not efficiently transmitted between humans. There are currently two classes of antiviral drugs against influenza: the neuraminidase inhibitors and the M2-ion channel blockers known as adamantanes. Studies have shown that neuraminidase inhibitors, in addition to being active against influenza A and B, may reduce complications of influenza in some individuals. H5N1 viruses isolated from poultry and humans in Asia in 2004 are known to be resistant to the adamantanes. The development of new anti-influenza drugs with broad activity and diminished risks of resistance emergence is of great importance.

**Goals:**

- Partner with industry, academia, and other interested parties to develop new influenza antiviral agents that can that can provide an option for therapy and chemoprophylaxis if strains that are resistant to currently available agents emerge and spread.
- Examine various treatment strategies to guide decision-making around the use of limited antiviral supplies.

**Ongoing HHS activities:**

- Evaluating monotherapy vs. combination therapy in the treatment of novel influenza infections
- Developing novel long-acting neuraminidase inhibitors
- Developing novel therapeutics using inhibitors of fusion proteins that may be capable of blocking infections by all strains of influenza viruses
- Investigating RNA interference of influenza virus infection as a new way of preventing and treating influenza infection
- Supporting “Immune Modeling Centers” which develop computational models to screen novel compounds for future clinical applications against influenza infection
- Supporting a clinical trial infrastructure (e.g., networks of potential sites with appropriate communication, documentation, and collaboration) to evaluate new influenza antiviral drugs

*In the event of a pandemic, antiviral drugs will be the first line of defense before a vaccine is available and could delay the spread of the pandemic.*

**Future priorities:**

- Expand preclinical and clinical support for the development of new promising antiviral drugs against influenza.
- Monitor for the emergence of antiviral resistance.
- Conduct studies to improve programmatic feasibility of stockpiling antiviral drugs.
- Conduct clinical trials of potentially resource-sparing approaches such as dose reduction and shortened treatment courses that might contribute to the testing of new public health strategies.
- Develop inhaled antibodies for immunoprophylaxis against influenza.
- Support continued development of other agents with activity against influenza including hemagglutinin inhibitors, polymerase inhibitors, and protease inhibitors.
- Study antiviral drug efficacy in severely ill hospitalized patients (including treatment started late in disease course).
- Study antiviral drug effects on severe influenza complications.
- Evaluate safety and dosing in infants with influenza, and alternative dosing regimens/formulations for infants and young children.
- Establish a pregnancy registry to prospectively collect data on exposures and outcomes.

**G. Vaccine development**

When the next influenza pandemic emerges, it will likely be caused by a type of influenza virus to which humans have little to no previous exposure. Vaccination offers one of the most effective measures for minimizing the morbidity and mortality of influenza. Inactivated influenza vaccines were developed more than 50 years ago, and since that time, annual vaccination with the inactivated vaccine has been the primary method by which the disease burden of influenza has been reduced. While influenza vaccines work well in the majority of people, they often do not work as well in the very young, the very old, or in patients with a compromised immune system. A live, attenuated vaccine against influenza was licensed in 2003 for use in individuals 5 to 49 years of age. During a pandemic with a novel influenza virus, public health officials will be confronted with making critical decisions about the vaccine dosage level and immunization regimen for various populations.

Vaccines produced in the event of the emergence and spread of a new pandemic influenza strain must be safe, able to be produced in large quantities and delivered quickly, and protect the largest number of individuals possible. Currently available influenza vaccines are produced by growing influenza viruses in embryonated chicken eggs, and take from 6 to 9 months to prepare. The rapid production and clinical evaluation of investigational lots of pandemic vaccines is an urgent global public health priority.

**Goals:**

- Increase availability of safe, effective, licensed pandemic influenza vaccines.
- Expand the repository of available vaccines, including those with varying potencies.

**Ongoing HHS activities:**

- Preparing of reference viruses of pandemic potential
- Preparing candidate vaccine reassortant strains for inactivated and live attenuated vaccines

*Vaccines produced in the event of the emergence and spread of a new pandemic influenza strain must be safe, able to be produced in large quantities and delivered quickly, and protect the largest number of individuals possible.*

- Supporting preclinical and clinical studies of pandemic (e.g., H5N1, H9N2) inactivated and live attenuated vaccines
- Establishing small clinical trial networks in Southeast Asia in collaboration with WHO and others
- Developing alternatives to egg-based vaccine manufacturing technologies, which include cell culture-based systems, recombinant proteins, DNA-based platforms
- Developing common antigen vaccines, which could offer protection from multiple influenza viruses, including M2 Peptide-based vaccines
- Developing alternative mechanisms of vaccine administration, including nasal gel, topical patches, and self-administered vaccines
- Developing antigen-sparing strategies
- Supporting "Immune Modeling Centers" that use computational models to predict human immune responses to influenza and to test novel vaccine strategies
- Investigating genetic characteristics of influenza A and B viruses that influence virus yield in eggs and tissue culture

**Future priorities:**

- Evaluate strategies to enhance the yield of production of influenza vaccine using current manufacturing processes.
- Support the production and evaluation of investigational lots of pandemic vaccines, including those likely to be of greatest risk, to assess safety and immunogenicity in various populations.
- Continue development of new influenza vaccines, including those that may provide longer-term and/or broader protection.
- Assess the potency of existing vaccines against combinations of traditional vaccine targets, e.g., HA and NA from different strains.
- Explore the potential of more highly conserved viral genes as targets of vaccination, and the efficacy of combination strain vaccine.
- Develop gene-based vaccines against influenza.
- Assess the potential contribution of cellular immunity and broader cross-protection that may be provided by vaccination.
- Monitor the long-term sequelae of vaccination, including the possible protective role of vaccination against non-infectious diseases such as cardiovascular, neurological, and other diseases.
- Develop mass vaccination/delivery techniques.
- Develop common protein vaccines.
- Develop investigational live attenuated influenza virus vaccine candidates for all 16 antigenic subtypes of HAs (H1 to H16).



*Performing clinical research during a pandemic offers a unique opportunity for gaining critical information about novel influenza infections.*

## H. Research resources and training

Supporting the availability of research resources is essential to facilitate advances in basic and translational research on influenza. These resources include providing research reagents and access to genomic and immunologic databases, animal models for preclinical drug and vaccine development, and biocontainment laboratories.

### Goals:

- Regularly update and expand reagents and influenza virus sequence data available to the worldwide research community.
- Expand the number of well-trained investigators who have influenza research or surveillance as a primary focus.

### Ongoing HHS activities:

- Preparing antibodies and reference antigens to avian influenza viruses considered to be of high pandemic potential
- Development of diagnostic tests such as real-time PCR for rapid diagnosis of potential pandemic viruses
- Training of Public Health Laboratories in detection and characterization of potential pandemic viruses (courses and bench training of national and international laboratorians)
- Conducting animal influenza surveillance training courses in Asia
- Supporting the Influenza Genome Sequencing Project to determine the complete genetic sequences of thousands of influenza virus isolates and to rapidly provide these sequence data to the scientific community

### Future priorities:

- Produce purified reference antigens to each of the 16 novel influenza virus hemagglutinins and to selected neuraminidase molecules.
- Prepare subtype-specific reference antisera (monoclonal and/or polyclonal antibodies) to avian hemagglutinin and neuraminidase proteins for use in the rapid identification of novel viruses and vaccine standardization.
- Produce a series of oligonucleotide primers to conserved regions of influenza virus genomes. These primers would allow for the rapid sequencing, identification, and characterization of novel influenza virus strains.
- Establish mechanisms that facilitate collaboration among international laboratories, which could result in the sharing of reagents, virus strains, data, new technologic advances, and training of laboratory personnel.

## I. Research priorities during a pandemic

In the face of novel infections including novel influenza viruses, the optimal treatment and public health management is not clear. In the absence of clinical trials evaluating a pandemic strain, anecdotal experience is often extrapolated to mandates on standards of care, even if the intervention has no proven utility and may be harmful. Performing clinical research during a pandemic offers a unique opportunity for gaining critical information about novel influenza infections. The information gained may help minimize the impact of future epidemics.

**Goals:**

- Provide public health policy-makers with data to guide a pandemic response.
- Provide clinicians with scientific data to justify recommended treatments, vaccines, or other interventions.

**Future priorities:**

- Evaluate change in natural history of disease and effect of antiviral drugs (including possible dosing changes, resistance emergence, adverse events and risk/benefit assessment, etc.) in management of pandemic strain compared to previously circulating strains.
- Evaluate the safety and immunogenicity of different doses of pandemic influenza vaccines in various populations.
- Assess risk factors for infection and person-to-person transmission.
- Evaluate the population impact of outbreaks early in the development of a pandemic.
- Evaluate the effect of interventions such as travel restrictions or school closings during outbreaks early in the development of a pandemic.
- Evaluate the effect of early use of antiviral drugs in high-risk patients.
- Evaluate the efficacy of the pandemic vaccine.
- Evaluate the impact of vaccination on pathogenesis and transmission.
- Evaluate the characteristics of diagnostic tests.
- Continue other ongoing research priorities (discussed in previous sections) to the extent compatible with the pandemic situation.
- Evaluate infection control measures to prevent or minimize the spread of pandemic influenza within healthcare settings.

**J. Research priorities after a pandemic**

Since influenza is a global infection affecting multiple species, it is unlikely that influenza can ever be eradicated. It is likely that future pandemics that occur will continue to affect people. Therefore, critical examination of plans, responses, and outcomes of the pandemic may afford information that could affect planning and minimize impact of future pandemics.

**Goal:**

- Evaluate the effectiveness of policies and procedures used in the pandemic.

**Future priorities:**

- Detail the "natural history" of the pandemic.
- Compare the effectiveness of different infection control policies.
- Determine the factors that influenced vaccination strategies.
- Compare different vaccine delivery systems for mass vaccination.
- Determine the different rates and risk factors for adverse events to pandemic strain of influenza vaccine.
- Evaluate antiviral and vaccination strategies.
- Assess adverse events related to antivirals and vaccines.
- Evaluate the most effective disease surveillance strategies.



# appendix H: international partnership on avian and pandemic influenza

The newly formed International Partnership on Avian and Pandemic Influenza (IPAPI), announced by President Bush at the United Nations General Assembly on September 14, 2005, brings together countries that share a set of core principles to generate and coordinate political momentum for addressing avian and pandemic influenza. With commitment from the highest political levels in countries around the world, IPAPI will strive to improve international surveillance, transparency, timeliness, and response capabilities and facilitate sharing of epidemiological information and samples critical for the response effort.

The Senior Officials Meeting of IPAPI, held in Washington, DC, on October 7, 2005, launched the Partnership and led to a jointly developed plan of action for coordinating national activities, evaluating national capabilities and filling gaps. This plan, based on the partnership's core principles (below), will supplement ongoing and planned international efforts and support the work of the relevant international organizations, including the World Health Organization (WHO), the World Animal Health Organization (OIE), the United Nations Food and Agriculture Organization (FAO), and other international and regional bodies and the private sector, NGOs, and others.

At the first meeting of IPAPI **over 80 countries and 8 international organizations came together, endorsing the core principles and agreeing to follow up on a number of major policy issues** that need further discussion at the highest political levels to resolve concerns or gain true consensus so that necessary movement can occur. A summary document that identifies the issues of greatest policy significance for dealing with the threats of avian and pandemic influenza was developed. Sub-groups of partners will deal with these, so that by the middle of 2006, progress made in raising the political attention on the problem and addressing the issues identified will be reported. Countries will convene the meetings of the sub-groups to focus on the issues identified. These sub-groups will coordinate with the relevant international organizations on technical matters. The sub-groups will identify any gaps needing further attention, and additional sub-groups may form to address issues as they arise.

The **Core Principles** that underpin the Partnership are:

1. International cooperation to protect the lives and health of our people;
2. Timely and sustained high-level global political leadership to combat avian and pandemic influenza;
3. Transparency in reporting of influenza cases in humans and in animals caused by strains that have pandemic potential, to increase understanding, preparedness, and especially to ensure rapid and timely response to potential outbreaks;
4. Immediate sharing of epidemiological data and samples with the World Health Organization (WHO) and the international community to detect and characterize the nature and evolution of any outbreaks as quickly as possible by utilizing, where appropriate, existing networks and mechanisms;

*Since pandemics are diseases without borders, the influenza virus will not respect political or geographic boundaries—a threat against one nation is a threat against the entire world.*

5. Rapid reaction to address the first signs of accelerated transmission of H5N1 and other highly pathogenic influenza strains so that appropriate international and national resources can be brought to bear;
6. Prevent and contain an incipient epidemic through capacity building and in-country collaboration with international partners;
7. Work in a manner complementary to and supportive of expanded cooperation with and appropriate support of key multilateral organizations (WHO, Food and Agriculture Organization, World Organization for Animal Health);
8. Timely coordination of bilateral and multilateral resource allocations, dedication of domestic resources (human and financial), improvements in public awareness, and development of economic and trade contingency plans;
9. Increased coordination and harmonization of preparedness, prevention, response, and containment activities among nations, complementing domestic and regional preparedness initiatives and encouraging where appropriate the development of strategic regional initiatives;
10. Actions based on the best available science.

This Partnership will help us improve international surveillance, transparency, timeliness, and response capabilities. Since pandemics are diseases without borders, the influenza virus will not respect political or geographic boundaries—a threat against one nation is a threat against the entire world. This initiative will strive for complete transparency, rapid response capabilities, cooperative surveillance, and will facilitate the sharing of epidemiological data and samples with each other and with the relevant international organizations. This will give us commitment from the highest political levels in countries around the world to adhere to these principles.

#### **Future activities**

In addition to participating in IPAPI, HHS will continue to work with other governments, international organizations such as GHSAG and WHO, the newly appointed UN Secretary-General's Special Representative on Pandemic Influenza, and other U.S. agencies individually as part of the overall USG international strategy. We will pursue a diplomatic strategy and provide technical assistance to affected countries and countries at risk. We will provide additional funding in FY 06 and thereafter, building on the work we are doing now in Southeast Asia. We expect to broaden our coverage to other parts of the globe. We will continue to look for increasing human-to-human transmission anywhere in the world as a triggering event for initiating a pandemic response by the U.S. HHS will pursue a prevention approach if possible, and a containment strategy where feasible—acting in concert with WHO and other nations as appropriate. At the core of this strategy, basic public health measures will be essential in reducing transmission in affected countries.



# appendix I: acronym list

## Abbreviations and Acronyms

|             |                                                                 |
|-------------|-----------------------------------------------------------------|
| ACF.....    | Administration for Children and Families                        |
| ACIP.....   | Advisory Committee on Immunization Practices                    |
| ASH.....    | Assistant Secretary for Health                                  |
| ASPA.....   | Assistant Secretary for Public Affairs                          |
| ASPHEP..... | Assistant Secretary for Public Health Emergency Preparedness    |
| ASTHO.....  | Association of State and Territorial Health Officials           |
| CDC.....    | Centers for Disease Control and Prevention                      |
| CONOPS..... | Concept of Operations                                           |
| DHS.....    | Department of Homeland Security                                 |
| DoD.....    | Department of Defense                                           |
| EOC.....    | Emergency Operations Center                                     |
| ESF.....    | Emergency Support Function                                      |
| FDA.....    | Food and Drug Administration                                    |
| FEMA.....   | Federal Emergency Management Agency                             |
| FMCS.....   | Federal Medical Contingency Stations                            |
| HA.....     | hemagglutinin (a protein on the surface of the influenza virus) |
| HHS.....    | Department of Health and Human Services                         |
| HRSA.....   | Health Resources and Services Administration                    |
| HSPD.....   | Homeland Security Presidential Directive                        |
| ICS.....    | Incident Command System                                         |
| IIMG.....   | Interagency Incident Management Group                           |
| ILI.....    | influenza-like-illness                                          |
| IOM.....    | Institute of Medicine                                           |
| NA.....     | neuraminidase (a protein on the surface of the influenza virus) |
| NI.....     | neuraminidase inhibitors                                        |

NIC.....National Influenza Center  
 NIH .....National Institutes of Health  
 NDMS.....National Disaster Medical System  
 NIMS .....National Incident Management System  
 NRP.....National Response Plan  
 NVAC.....National Vaccine Advisory Committee  
 NVPO/HHS.....National Vaccine Program Office, Department of Health and Human Services  
 OPHEP/HHS .....Office of Public Health Emergency Preparedness, Department of Health and Human Services  
 OGHA/HHS .....Office of Global Health Affairs, Department of Health and Human Services  
 OIGA/HHS .....Office of Intergovernmental Affairs, Department of Health and Human Services  
 PHS.....Public Health Service  
 PPE.....Personal Protective Equipment  
 R&D .....Research and Development  
 SARS.....Severe Acute Respiratory Syndrome  
 USAID.....U.S. Agency for International Development  
 USDA.....U.S. Department of Agriculture  
 VRBPAC .....Vaccine and Related Biological Products Advisory Committee  
 WHO.....World Health Organization





# appendix J: internet resources on pandemic influenza

The links listed below were active as of October 2005. However, because Web sites can change without notice, no site can be guaranteed active or accurate indefinitely.

## U.S. Government

[www.pandemicflu.gov](http://www.pandemicflu.gov)

## Nongovernmental Organizations

Association of State and Territorial Health Officials (ASTHO) – [www.astho.org](http://www.astho.org)

Infectious Disease Society of America – [www.idsociety.org](http://www.idsociety.org)

National Foundation for Infectious Diseases – [www.nfid.org](http://www.nfid.org)

Institute of Medicine (IOM) – [www.iom.edu](http://www.iom.edu)

World Health Organization (WHO) – [www.who.org](http://www.who.org)

## Influenza background information

**CDC** – Presents information on the symptoms, treatment, and complications of the disease, prevention and control, the types of influenza viruses, questions and answers on symptoms, vaccination, and myths. [www.cdc.gov/flu](http://www.cdc.gov/flu)

**National Vaccine Program Office** – Presents a historical overview of pandemics that occurred throughout the past century (Spanish Flu, Asian Flu, Hong Kong Flu), and three influenza scares (Swine Flu, Russian Flu, and Avian Flu). [www.dhhs.gov/nvpo/pandemics](http://www.dhhs.gov/nvpo/pandemics)

**World Health Organization** – Defines an influenza pandemic, explains how a new influenza virus can cause a pandemic, presents the consequences of an influenza pandemic, explains the global surveillance systems, and provides links to other pandemic plans from other nations. [www.who.int/csr/disease/influenza/pandemic/en](http://www.who.int/csr/disease/influenza/pandemic/en)

## Additional response resources

**HRSA Bioterrorism and Emergency Preparedness Grants and Cooperative Agreements** – Provides information about HRSA programs for bioterrorism and emergency preparedness activities available for state and local jurisdictions. [www.hrsa.gov/bioterrorism](http://www.hrsa.gov/bioterrorism)

*[www.pandemicflu.gov](http://www.pandemicflu.gov)*



**The Public Health Preparedness and Response Capacity Inventory** – Provides a resource for state and local health departments undertaking comprehensive assessments of their preparedness to respond to bioterrorism, outbreaks of infectious disease, or other public health threats and emergencies. [www.dhs.ca.gov/epo/PDF/NPSsmpxv1.pdf](http://www.dhs.ca.gov/epo/PDF/NPSsmpxv1.pdf)

**CDC Cooperative Agreements on Public Health Preparedness** – Provide funding to state and local public health jurisdictions for preparedness for and response to bioterrorism, other outbreaks of infectious diseases, and other public health threats and emergencies. [www.bt.cdc.gov/planning/continuationguidance](http://www.bt.cdc.gov/planning/continuationguidance)

**Epidemic Information Exchange** – Provides a secure, web-based communications network for information exchange among CDC, state and local health departments, and other public health professionals. [www.cdc.gov/mmwr/epix/epix.html](http://www.cdc.gov/mmwr/epix/epix.html)

**Centers for Public Health Preparedness** – A national system for competency-based training tools for the public health workforce. [www.asph.org/acphp](http://www.asph.org/acphp)

**Strategic National Stockpile** – Provides information on the availability and rapid deployment of life-saving pharmaceuticals, antidotes, other medical supplies, and equipment necessary to counter the effects of nerve agents, biological pathogens, and chemical agents. [www.bt.cdc.gov/stockpile](http://www.bt.cdc.gov/stockpile)

**Smallpox Response Plan and Guidelines (Version 3.0)** – Presents the most current criteria for implementation of CDC smallpox response plan, notification procedures for suspected smallpox cases, CDC and state/local responsibilities and action in the event of a smallpox outbreak, vaccine mobilization and deployment, and CDC personnel mobilization and deployment. [www.bt.cdc.gov/agent/smallpox/response-plan](http://www.bt.cdc.gov/agent/smallpox/response-plan)

**FDA, Center for Biologics Evaluation and Research** – Discussion of influenza vaccines and related information. [www.fda.gov/cber/flu/flu.htm](http://www.fda.gov/cber/flu/flu.htm)

**FDA, Center for Drug Evaluation and Research** – Discussion of influenza antiviral drugs and related information. [www.fda.gov/cder/drug/antivirals/influenza](http://www.fda.gov/cder/drug/antivirals/influenza)

# part 2

---

## Public Health Guidance for State and Local Partners







# introduction

## TABLE OF CONTENTS

|                                                                                                            |            |
|------------------------------------------------------------------------------------------------------------|------------|
| <b>A. INTRODUCTION .....</b>                                                                               | <b>I-2</b> |
| Purpose and Aims .....                                                                                     | I-2        |
| Organization .....                                                                                         | I-3        |
| <b>B. OVERVIEW OF PLANNING BY STATE AND LOCAL GOVERNMENTS .....</b>                                        | <b>I-3</b> |
| Planning Process .....                                                                                     | I-4        |
| Legal Preparedness .....                                                                                   | I-5        |
| <b>C. OVERVIEW OF COMMUNITY-WIDE PLANNING TO SUPPORT HEALTHCARE FACILITIES .....</b>                       | <b>I-5</b> |
| Community Planning in Rural Areas .....                                                                    | I-6        |
| <b>D. PUBLIC HEALTH GUIDANCE SUPPLEMENTS .....</b>                                                         | <b>I-6</b> |
| Box 1. Issues for State and Local Partners that Will Require Real-time Guidance during<br>a Pandemic ..... | I-10       |
| Box 2. Establishing a Pandemic Influenza Coordinating Committee for<br>State-level Planning .....          | I-11       |
| Box 3. Influenza: Information and Definitions .....                                                        | I-12       |
| Appendix 1. Checklist of Legal Considerations for Pandemic Influenza in<br>Your Community .....            | I-13       |
| Appendix 2. Fact Sheet: Practical Steps for Legal Preparedness .....                                       | I-16       |

## PART 2. PUBLIC HEALTH GUIDANCE ON PANDEMIC INFLUENZA FOR STATE AND LOCAL PARTNERS<sup>1</sup>

### A. Introduction

An influenza pandemic may emerge with little warning, affecting a large number of people within a short space of time. During the first wave of the pandemic, outbreaks may occur simultaneously in many locations throughout the nation, preventing a targeted concentration of national emergency resources in one or two places—and requiring each locality to depend in large measure on its own resources to respond. A vaccine will not yet be available, and the supply of antiviral drugs will be limited. Local outbreaks may last for weeks or months, and widespread illness in a particular community could lead to shortages in the healthcare sector as well as in essential services.

An effective local response will depend on pre-established partnerships and collaborative planning by public health officials, hospital administrators, and community leaders, who have considered a range of best-case and worst-case scenarios. It will require flexibility and real-time decision-making, guided by epidemiologic information on the pandemic virus. It will also depend on a well-informed public that understands the dangers of pandemic influenza and accepts the potential need for control measures like self-isolation and quarantine that prevent disease spread by reducing social contact. The public must also understand and accept the rationale in prioritizing the use of limited supplies of antiviral drugs and initial stocks of vaccines.

The goal of Part 2 of the *HHS Pandemic Influenza Plan* is to help state and local jurisdictions and healthcare facilities mount an effective response to pandemic influenza. Public Health Guidance on Pandemic Influenza for State and Local Partners was developed with input from many public health and medical partners with front-line responsibility for pandemic influenza response.

### Purpose and Aims

All U.S. state, local, and tribal governments must be prepared to detect the earliest cases of disease, to minimize illness and morbidity, and to decrease social disruption and economic loss. The principle aims of the *Public Health Guidance for State and Local Partners* are to:

- Provide guidance for updating state-level pandemic influenza response plans developed in fulfillment of activities under the CDC and HRSA Cooperative Agreements for Public Health Emergency Preparedness and Bioterrorism Hospital Preparedness ([www.bt.cdc.gov/planning/guidance05/index.asp](http://www.bt.cdc.gov/planning/guidance05/index.asp) and [www.hrsa.gov/grants/preview/guidancespecial/hrsa05001.htm](http://www.hrsa.gov/grants/preview/guidancespecial/hrsa05001.htm)).
- Help healthcare partners address the medical challenges of pandemic influenza (e.g., evaluation and management of large numbers of patients, occupational health risks, and limited supplies of antiviral medications and vaccines).
- Define the public health role in healthcare planning and preparedness for pandemic influenza.
- Strengthen linkages between public health departments and private sector partners—including healthcare facilities, community-based organizations, clinical laboratories, behavioral health experts, and first responders—to protect health and preserve essential services during a pandemic.

Many activities described in the Public Health Guidance for State and Local Partners are similar, if not the same as those required to combat other infectious diseases, such as Severe Acute Respiratory Syndrome (SARS) or intentionally-spread smallpox or plague. Topics covered in the *Public Health Guidance for State and Local Partners* may, therefore, be relevant to—or addressed in—other emergency preparedness plans. (See, for example: *Public Health Guidance for Community-Level Preparedness and Response to SARS*: [www.cdc.gov/ncidod/sars/guidance/](http://www.cdc.gov/ncidod/sars/guidance/); *Smallpox Response Plan and Guidelines*: [www.bt.cdc.gov/agent/smallpox/response-plan/index.asp](http://www.bt.cdc.gov/agent/smallpox/response-plan/index.asp)).

<sup>1</sup> Through this document, the term “state and local” is inclusive of territorial and tribal governments and health authorities, as applicable.



## Organization

Part 2 of the *HHS Pandemic Influenza Plan* provides an overview of

- Pandemic influenza preparedness and response planning by state and local governments (Section B)
- Community planning to support healthcare facilities on a city-wide or regional basis during an influenza pandemic (Section C)

Part 2 also includes eleven supplements that provide guidance on specific aspects of pandemic influenza planning and response:

- Supplement 1: Pandemic Influenza Disease Surveillance
- Supplement 2: Laboratory Diagnostics
- Supplement 3: Healthcare Planning
- Supplement 4: Infection Control
- Supplement 5: Clinical Guidelines
- Supplement 6: Vaccine Distribution and Use
- Supplement 7: Antiviral Drug Distribution and Use
- Supplement 8: Community Disease Control and Prevention
- Supplement 9: Management of Travel-Related Risk of Disease Transmission
- Supplement 10: Public Health Communications
- Supplement 11: Psychosocial Workforce Support Services

The content of each supplement is summarized in Section D.

Priority activities in each Supplement are organized under the time periods laid out in the WHO classification system proposed in February 2005: the *Interpandemic Period*, the *Pandemic Alert Period*, and the *Pandemic Period*. Some of the Supplements further subdivide Pandemic Period activities according WHO pandemic phases or to local levels of disease spread that will trigger particular activities over the course of the pandemic.

To help state and local public health and healthcare partners prepare for the unexpected, the *Public Health Guidance for State and Local Partners* includes a list of cross-cutting technical resources, including exercises and drills, to facilitate the exploration of different scenarios and local concerns (see **Supplement 3. Healthcare Planning**, Appendix 1). The *Public Health Guidance for State and Local Partners* also identifies disease-control issues whose resolution will require real-time guidance during a pandemic (Box 1).

Definitions of public health terms used throughout the *Public Health Guidance for State and Local Partners* are provided in Box 3 and in the Glossary.

## B. Overview of Planning by State and Local Governments

All states and localities must be prepared to coordinate the pandemic influenza response within and between their jurisdictions. State and local responsibilities include:

- Enhancing disease surveillance to ensure early detection of the first cases of pandemic influenza in their jurisdictions (see **Supplements 1 and 2**).

- Distributing public stocks of antiviral drugs and vaccines and providing local physicians and hospital administrators with updated guidance on clinical management and infection control as the situation unfolds (**Supplements 3 to 7<sup>2</sup>**)
- Preventing local disease transmission using a range of containment strategies (**Supplements 8 and 9**)
- Providing ongoing communication with the public (about the response effort, including the purpose and duration of containment measures) (**Supplement 10**)
- Providing psychological and social support services to emergency field workers and other responders (**Supplement 11**)

As described in Part 1, the HHS will support affected states or jurisdictions during an influenza pandemic by:

- Conducting outbreak investigations, as requested
- Conducting epidemiologic and laboratory-based studies ("special studies")
- Providing ongoing information from the national influenza surveillance system on the pandemic's impact on health and the healthcare system
- Expanding supply of antiviral drugs by stimulating increased U.S. based production capacity
- Expanding U.S.-based production capacity for pandemic vaccine and working with manufacturers to ensure that pandemic vaccine is produced at full capacity
- Distributing public stocks of antiviral drugs and other medical supplies from the Strategic National Stockpile to the states
- Distributing public stocks of vaccines, when they become available
- Providing guidance on community containment strategies, including travel restrictions, school closings, and quarantine
- Communicating with the public via the news media
- Monitoring the response

## Planning Process

The first step in the planning process for state and local governments is to establish a Pandemic Influenza Coordinating Committee to oversee preparedness planning and ensure integration with other emergency planning efforts. The membership of the Coordinating Committee should represent a range of disciplines and expertise in the public and private sectors (Box 2).

The Coordinating Committee should draft and formally adopt a pandemic influenza response plan that:

- Delineates the roles and responsibilities of state and local agencies and offices
- Builds on existing preparedness and response plans for bioterrorism events, SARS, and other infectious disease emergencies
- Addresses legal issues including those that affect hospital staffing, patient care, and quarantine (see below)
- Is periodically reviewed and updated

As part of the planning effort, the Coordinating Committee should:

- Help establish and promote community-based task forces that support healthcare institutions on a city-wide or regional basis (see Section C).
- Identify the authority responsible for state-level declaration of a public health emergency and for officially activating the pandemic influenza response plan.

<sup>2</sup> Supplements 3, 4, and 5 are primarily directed to healthcare providers and hospital administrators, while Supplements 6 and 7 are also directed to state and local health officials.

- Identify an overall coordinator to work with hospitals and communicating with medical and mental health personnel during a pandemic.
- Identify the jurisdiction's controlling authority over intrastate and interstate modes of transportation, which might be curtailed during a pandemic.
- Identify state and local law enforcement personnel who will assist in maintaining public order and enforcing control measures during a pandemic.
- Develop and reinforce relationships with local health authorities in adjoining jurisdictions.
- Make planning decisions on acquisition and distribution of antiviral drugs and vaccines, in accordance with HHS recommendations.
- Ensure that plans take into account tribal populations, where applicable.
- Conduct state-level "table top" exercises to test response capabilities.
- Encourage local jurisdictions to conduct exercises and drills.

## Legal Preparedness

The Coordinating Committee should review state and local statutory provisions regarding:

- Laws and procedures for closing businesses or schools and suspending public meetings during a declared state of emergency
- Medical volunteer licensure, liability, and compensation laws for in-state, out-of-state, and returning retired and non-medical volunteers
- Quarantine laws and how they apply in a public health emergency
- Workers' compensation laws as they apply to healthcare workers and workers who provide essential services
- Reimbursement for workers placed in isolation or quarantine (if not addressed in sick leave policies)

Relevant federal law should be reviewed as well and statutes should be harmonized, as feasible.

Additional information on legal preparedness is provided in Appendices 1 and 2.

## C. Overview of Community-wide Planning to Support Healthcare Facilities

Without special preparation, a large-scale pandemic could quickly overwhelm local healthcare facilities and resources. Although institutional planning by hospitals is essential (see Supplement 3), it is not sufficient. Hospitals depend on many organizations and groups—e.g., suppliers of food, drugs, and medical supplies, sanitation workers, and telephone companies—to accomplish their day-to-day tasks. If workforce illnesses and absences prevent these organizations from functioning normally during a pandemic, hospitals will be severely affected.

State health authorities should consider promoting the establishment of local pandemic influenza task forces that will ensure community readiness to provide emergency support to healthcare facilities on a city-wide or regional basis. Depending on the state, the task forces may be coordinated by municipal, county, or tribal health departments, or by regional public health offices. Task force activities should be integrated with state-wide planning efforts and should reflect common goals and principles for preparedness and response.

Each local task force should include representatives from hospitals, community service organizations, professional organizations of physicians, nurses, and pharmacists, home health care organizations, long term care facilities, federally qualified health centers (FQHC) and other healthcare safety net providers, emergency medical services (EMS), behavioral health

experts, and public health officials. The task forces should also include private sector partners who provide essential services such as food, electricity, and water. They may also include civil protection authorities such as the police, sheriff's departments, and firefighters.

During a pandemic, the task force would be responsible for coordinating health care activities within the community and should work with local health departments and hospitals to:

- Improve communication with medical care providers and health care organizations.
- Monitor local hospital resources (e.g., adult and pediatric hospital beds, intensive care unit beds, emergency department beds, medical supplies, respirators and other equipment, mortuary capacity).
- Address emergency healthcare staffing needs and other medical surge capacity issues.
- Encourage coordination among state and federal healthcare facilities, such as Veterans Administration hospitals, Indian Health Service facilities, and Department of Defense hospitals.
- Conduct contingency planning with:
  - Private sector groups that support hospital functions, to ensure continuity of operations during the pandemic. These groups may include medical supply companies, medical gas companies, companies that supply food and clean linens, and internet service providers.
  - Public utilities (water, electricity, gas, telephone, sanitation) to ensure continued service during the pandemic.
  - Local law enforcement agencies who can help maintain order if a hospital is overwhelmed by a large volume of patients (ill or worried about being ill).
  - Identify alternative care sites for patient care (child and adult) and sites for quarantine.
  - Identify community-based organizations that can provide psychological and social support to healthcare workers, public health field workers, and other emergency responders (see **Supplement 11**).

## Community Planning in Rural Areas

Special efforts should be made to address pandemic planning issues in rural communities and other areas where emergency rooms and other resources for urgent care and emergency treatment are lacking. Without community-wide planning, a surge of pandemic influenza patients could force the closure of local outpatient healthcare clinics. Planning partners may include healthcare providers at outpatient clinics, federally qualified health centers (FQHCs),<sup>3</sup> IHS and tribal health care facilities, and other healthcare safety net providers<sup>4</sup> that deliver care to low-income and other vulnerable populations.

## D. Public Health Guidance Supplements

The eleven Public Health Guidance supplements can be found on the following pages. An overview of each supplement is provided below.

**Supplement 1. Pandemic Influenza Surveillance** provides recommendations to state and local partners on virologic surveillance for influenza viruses and on epidemiologic (disease) surveillance to monitor the health impact of influenza

<sup>3</sup> A federally qualified health center (FQHC) is a type of provider defined by the Medicare and Medicaid statutes. FQHCs include health centers receiving grants under section 330 of the Public Health Service Act, certain tribal organizations, and clinics designated by HHS as FQHC Look-Alikes. More information may be found at: <http://www.cms.hhs.gov/providers/fqhc/>

<sup>4</sup> Health care safety net providers deliver care to low-income and other vulnerable populations, including the uninsured and those covered by Medicaid. Many of these providers have either a legal mandate or an explicit policy to provide services regardless of a patient's ability to pay (<http://www.ahcpr.gov/data/safetynet/faq.htm>). Major safety net providers include public hospitals and community health centers as well as teaching and community hospitals, and private physicians.

(outpatient, hospital, and mortality surveillance). The Interpandemic and Pandemic Alert Period recommendations focus on disease surveillance during regular influenza seasons, as well as on surveillance for human cases of infection with avian influenza A (H5N1) or other novel strains of influenza. They also address preparedness planning to lay the groundwork for enhanced disease surveillance during a pandemic.

The Pandemic Period Recommendations focus on surveillance activities that will be undertaken if a pandemic virus is reported overseas or if a pandemic virus emerges in or enters the United States. These activities include ongoing virologic surveillance to monitor genetic and antigenic changes in the pandemic virus, including changes in its drug susceptibilities.

**Supplement 2. Laboratory Diagnostics** provides recommendations to state and local public health partners on the use of diagnostic tests to detect, characterize, and monitor novel subtypes of influenza, including avian influenza A (H5N1) and other viruses with pandemic potential. The Interpandemic and Pandemic Alert Period recommendations focus on laboratory testing in support of seasonal influenza surveillance, on laboratory-based detection of novel subtypes of influenza, and on preparedness planning to support the laboratory component of the response to an influenza pandemic (e.g., detection and characterization of viruses, case reporting, specimen management, and surge capacity issues).

The Pandemic Period recommendations focus on provision of laboratory support for disease surveillance and for clinicians and hospitals. The Pandemic Period Recommendations also cover occupational health issues for laboratory workers.

**Supplement 3. Healthcare Planning** provides guidance to healthcare partners on developing effective institutional plans for responding to an influenza pandemic. It focuses on Interpandemic Period guidance for healthcare preparedness planning in such areas as pandemic influenza surveillance, incident management infrastructure, hospital communications, education and training, patient triage, clinical evaluation and admission, facility access, occupational health, vaccine and antiviral drug use, surge capacity, and mortuary issues. Also considered is planning for providing care in non-hospital settings including clinics, physician's offices, and the alternative care sites that will be set up if hospital-bed capacity is exceeded during a pandemic.

The Pandemic Period guidance recommendations focus on activation of institutional pandemic influenza response plans.

**Supplement 4. Infection Control** provides recommendations to healthcare and public health partners on basic principles of infection control for limiting the spread of pandemic influenza. These principles are common to the prevention of other infectious agents spread by respiratory droplets. Guidance is included on the selection and use of personal protective equipment, hand hygiene, safe work practices, cleaning and disinfection of environmental surfaces, handling of laboratory specimens, and postmortem care. The guidance also covers infection control practices related to the management of infectious patients, the protection of persons at high-risk for severe influenza or complications, and issues concerning occupational health.

Supplement 4 also provides guidance on how to adapt infection control practices in specific healthcare settings, including hospitals, nursing homes and other long-term care facilities, pre-hospital care (Emergency Medical Services), home healthcare, and medical offices and other ambulatory care settings. The section on hospital care covers detection of entering patients who may be infected with pandemic influenza, implementation of source-control measures to limit virus dissemination from respiratory secretions, hospitalization of pandemic influenza patients, and detection and control of nosocomial transmission. Supplement 4 also includes recommendations on infection control measures and care of pandemic influenza patients in the home, as well as in alternative care sites that may be established if local hospital capacity is overwhelmed by a pandemic.

Given some uncertainty about the characteristics of a new pandemic strain, all aspects of preparedness planning for pandemic influenza must allow for flexibility and real-time decision-making that take new information into account as the situation unfolds. If the new virus is unusual in transmissibility, virulence, or in any other way, HHS and its partners will provide state and local partners with updated infection control guidance.

**Supplement 5. Clinical Guidelines** focus on the initial screening and clinical assessment of patients who present from the community with fever and/or respiratory symptoms during the Interpandemic, Pandemic Alert, and Pandemic Periods. The Appendices include information on the clinical presentation and complications of influenza, the clinical features of human infection with avian influenza A (H5N1), and management of secondary bacterial pneumonia during a pandemic.

During the Interpandemic and Pandemic Alert Periods, early recognition of an illness caused by a novel influenza strain will rely on a combination of clinical and epidemiologic features. During the Pandemic Period (with a setting of high community prevalence) diagnosis will likely be more clinically oriented, as exposure history will become less helpful and the likelihood will be high that any severe influenza-like illness would be pandemic influenza.

**Supplement 6. Vaccine Distribution and Use** provides recommendations to state and local partners and other stakeholders on planning for the different elements of a pandemic vaccination program. The focus of the Interpandemic Period recommendations is on planning for vaccine distribution, vaccination of priority groups, adverse event monitoring, tracking of vaccine supply and administration, vaccine coverage and effectiveness studies, communications, legal preparedness, and training. The focus of Pandemic Period recommendations is on working with public health and healthcare partners to implement plans for vaccine distribution and use.

**Supplement 7. Antiviral Drug Distribution and Use** provides recommendations to state and local partners on the distribution and use of antiviral drugs for treatment and prophylaxis during an influenza pandemic. The Interpandemic and Pandemic Alert Period recommendations focus on preparedness planning for rapid distribution and use of antiviral drugs (e.g., procurement, distribution to priority groups, legal preparedness, training, and data collection on use, effectiveness, safety, and the development of drug resistance). The Interpandemic and Pandemic Alert Period recommendations also cover the use of antiviral drugs in management and containment of cases and clusters of infection with novel strains of influenza, including avian influenza A (H5N1) and human strains with pandemic potential.

The Pandemic Period recommendations focus on local use of antiviral drugs in three situations: when pandemic influenza is reported abroad, when there is limited transmission of pandemic influenza in the United States, and when there is widespread transmission in the United States. Recommendations for optimal use of limited stocks of antivirals will be updated throughout the course of an influenza pandemic, in accordance with new epidemiologic and laboratory data. National recommendations will also be updated as an effective pandemic influenza vaccine becomes available.

**Supplement 8. Community Disease Control and Prevention** provides recommendations to state and local partners on the use of disease containment strategies to prevent disease transmission at different phases of an influenza pandemic. The Interpandemic and Pandemic Alert Period recommendations focus on preparedness planning for implementation of containment measures. They also outline actions that may be taken during the earliest stage of a pandemic when the first potential cases or disease clusters are detected. In this setting, relatively intense individual-level containment measures (e.g., patient isolation and identification, monitoring, and quarantine of contacts) may be used without causing undue strain on limited public health and health care resources.

The Pandemic Period recommendations focus on measures that may be beneficial and practical when there is a large number of cases and extensive viral transmission. In such a setting, individual-level measures may no longer be effective or feasible (e.g., if hospital isolation beds can no longer accommodate all patients, if most contacts cannot be traced in time to prevent further exposures, or if staffing constraints make contact-tracing impractical). In that case, state and local health departments may consider measures that decrease social contact within groups or whole communities (e.g., quarantine of groups of exposed persons, cancellation of public events, snow days, self-shielding, or widespread community quarantine). Effective use of community containment measures during a pandemic will require continuous evaluation of such parameters as viral transmissibility, the number and geographic distribution of cases, the reproductive rate of epidemic propagation, and the nature and severity of illness.



**Supplement 9. Management of Travel-Related Risk of Disease Transmission** provides recommendations to state and local partners on travel-related containment strategies that may be employed during different phases of an influenza pandemic. These strategies range from distribution of health alert notices, to isolation and quarantine of new arrivals, to restriction or cancellation of nonessential travel. State and local health departments will implement these strategies in association with Quarantine Stations located at 11 ports of entry.

The Interpandemic and Pandemic Alert Period recommendations focus on preparedness planning, as well as on management of arriving ill passengers on international flights or cruise ships. The Pandemic Period recommendations focus on travel-related measures to prevent disease spread into, out of, or within the United States.

**Supplement 10. Public Health Communications** describes seven key risk communications concepts. During the Interpandemic Period, national, state, and local health communications professionals should focus on preparedness planning and on building flexible, sustainable communications networks. During the Pandemic Alert Period, they should work collaboratively to develop and disseminate consistent and accurate messages. During the Pandemic Period, they should focus on well-coordinated health communications to support public health interventions designed to help limit influenza-associated morbidity and mortality and to address related social and economic changes.

**Supplement 11. Psychosocial Workforce Support Services** addresses the psychological and social ("psychosocial") needs of occupational groups who participate in the response to an influenza pandemic. These groups include:

- Healthcare workers who provide medical care for the children and adults who fall ill
- Emergency field workers and other public health personnel who help control disease spread
- First responder or non-governmental organizations whose employees assist affected groups (e.g., quarantined persons or patients at home or in hospitals)
- Essential service workers whose activities maintain normal social functions and minimize social disruption
- The family members of all of these groups

Recommendations for the Interpandemic and Pandemic Alert Periods focus on institutionalization of psychosocial support services that help workers manage emotional stress and resolve personal, professional, and family issues related to the response to an influenza pandemic. They also cover preparation of informational materials for distribution to employees and their families during the emergency. Finally, they cover the development of Workforce Resilience Programs that include assistance for families of responders who may be deployed in the field and inaccessible for extended periods of time.

Recommendations for the Pandemic Period focus on delivery of psychosocial support services to response workers, on provision of occupational health information to healthcare providers, and on implementation of Workforce Resilience Programs.

## **BOX 1. ISSUES FOR STATE AND LOCAL PARTNERS THAT WILL REQUIRE REAL-TIME GUIDANCE DURING A PANDEMIC**

- What are the case definitions for suspected and confirmed cases of pandemic influenza? What types of epidemiologic data should be collected? (The answers may change over time, depending on the characteristics of the pandemic virus and the geographical spread of the pandemic.)
- What are the drug susceptibilities of the pandemic virus?
- What amounts of antiviral drugs are available to your state from public and private stocks?
- What amounts of pandemic influenza vaccine are available to your state from public stocks?
- Which groups of people are at greatest occupational and medical risk (i.e., what are the age-specific and occupational attack rates)? What modifications should be made to the national recommendations for distribution and use of antiviral drugs and vaccines to reflect this information?
- Which laboratory tests may be used locally for laboratory confirmation of pandemic-influenza cases? Which isolates should be sent to CDC for subtyping?
- How fast is the pandemic spreading in your area? What does local surveillance data on the number of hospitalizations and deaths suggest in regard to:
  - Distribution of hospital supplies and hospital beds on a regional or statewide basis
  - How fast local and regional hospital resources are being depleted
  - Implementation of school closings and other community containment measures
  - Situating and opening alternative care sites and quarantine facilities
  - Absentee rates at hospitals and at businesses that provide essential services
  - Impact of the outbreak on the public health and medical workforce
- Is anything unusual or unexpected? If so, should any modifications be made in infection control practices or in the detection or management?
- Is there evidence from statistical modeling that predicts where and how fast the pandemic will spread?

## **BOX 2. ESTABLISHING A PANDEMIC INFLUENZA COORDINATING COMMITTEE FOR STATE-LEVEL PLANNING**

### **Coordinating Committee members may include:**

- Representatives from the Governor's Office (supplemented by representatives of the mayor's office for large metropolitan areas)
- Representatives from local, county, or district health departments
- Representatives from territorial and tribal health departments
  - State Epidemiologist
  - State Laboratory Director
- Public Health Information Officer
- Public Affairs/Communications Officer
- Immunization Project Director
- State Strategic National Stockpile (SNS) Coordinator
- Representatives from:
  - State and Local Offices of Emergency Preparedness
  - State Mental Health Office
  - State Transportation Office
  - Office of the General Counsel at the state health department
- Representatives from HRSA and CDC

Membership of the Pandemic Influenza Coordinating Committee may overlap with state or local bioterrorism preparedness coordinating committees.

### **Stakeholders who provide input to the Coordinating Committee may include:**

- Infectious disease physicians
- Public health and private clinical laboratories
- Immunization program personnel
- State public health associations or state associations of county and city health officials
- State primary care associations representing health centers in the state
- Hospitals and other healthcare facilities, including VA Hospitals, DoD Hospitals, and Indian Health Service facilities
- Medical societies and nursing organizations
- Pharmacists
- Community immunizers
- Emergency medical services and emergency departments within hospitals
- Local media officials

### **Additional participants may include**

- Volunteer organizations involved in response and recovery to various disasters
- Social service agencies
- Law enforcement agencies
- Infectious disease experts from universities
- Funeral directors
- Local military installations
- Large industries or employers in the area
- State aviation authorities
- Representatives of public utilities
- Education administrators

## **BOX 3. INFLUENZA: INFORMATION AND DEFINITIONS**

### **Influenza**

- Influenza is an acute viral disease of the respiratory tract characterized by fever, headache, myalgia, prostration, coryza, sore throat, and cough. Otitis media, nausea, and vomiting are also commonly reported among children.
- For surveillance purposes, influenza-like illness (ILI) is defined as respiratory illness with temperature greater than 38°C plus either sore throat or cough.

### **Seasonal or Interpandemic Influenza**

- Seasonal influenza occurs each winter, primarily causing self-limiting disease for 2 to 7 days in most infected individuals. Influenza complications—especially viral and bacterial pneumonias—can cause severe illness or death in infants, the elderly, the immunocompromised, and those with certain chronic medical conditions.
- As seasonal influenza viruses replicate and evolve, they develop small changes in their surface antigens that allow them to evade existing immunity to influenza in the human population. Influenza vaccines must therefore be reformulated each year to provide protection against currently circulating strains of influenza A and B.

### **Pandemic Influenza**

- Pandemic influenza is an uncommon type of influenza A that causes greater morbidity and mortality than seasonal influenza. An influenza pandemic occurs when a new influenza A virus (a “pandemic influenza virus”) emerges in the human population, causes serious illness, and then spreads easily from person to person worldwide. Influenza pandemics occurred three times during the twentieth century—in 1918, 1957, and 1968.

### **Novel Strains of Influenza**

- Novel strains of influenza are newly identified influenza viruses that require close monitoring to determine whether they (or their genetic offshoots) are capable of pandemic spread. They may include avian or animal influenza strains that can infect humans (like avian influenza A [H5N1]), or new, or re-emergent, human viruses that cause cases or clusters of human disease.

## APPENDIX 1. CHECKLIST OF LEGAL CONSIDERATIONS FOR PANDEMIC INFLUENZA

The following checklist is a planning tool highlighting the relevant partners, resources, planning considerations, due process considerations, and issues of legal liability and immunity that may arise in the context of pandemic influenza. Next to each consideration are listed the legal partners (e.g., public health, hospitals, public safety, emergency management, judiciary) who may be called upon to address these considerations as part of the affected community's response. The challenge of the public health response is to protect the health of many, while safeguarding the rights of the individual. An integrated and coordinated response by attorneys at all levels in the community is essential to achieving this goal.

The checklist format is not intended to set forth mandatory requirements or establish a national standard for legal preparedness. Each state and local jurisdiction should determine for itself whether it is adequately prepared for disease outbreaks in accordance with its own laws and procedures. Relevant federal law also should be reviewed and statutes harmonized, as feasible.

### Planning Considerations

- ☐ Ensure that public health personnel have a basic understanding of the intersection among federal, state, local, and tribal laws regarding quarantine and isolation as they relate to international airports and interstate border crossings. [public health/public safety/emergency management]
- ☐ Where applicable, draft or update legal orders, motions, and templates requiring medical evaluation of non-compliant persons who meet the pandemic influenza case definition and have symptoms of pandemic influenza. [public health/hospitals]
- ☐ Ensure that legal counsel has reviewed the feasibility of requiring persons to self-monitor for medical conditions (e.g., temperature checks) and (where applicable) drafted legal orders or agreements. [public health]
- ☐ Ensure that legal counsel has reviewed the feasibility of issuing "exclusion" orders (i.e., excluding contacts from using public transportation, attending public meetings) and, where applicable, drafted templates and legal orders. [public health/public safety/emergency management]
- ☐ Ensure the existence of a statute, regulation, or other administrative mechanism authorizing isolation/quarantine for pandemic influenza. [public health/public safety/judiciary]
- ☐ Draft legal orders, motions, and templates for isolation/quarantine in homes, hospitals, or other designated facilities. [public health/hospitals/emergency management/public safety]
- ☐ Ensure that legal counsel has reviewed the feasibility of using electronic methods to monitor suspected non-compliant individuals in home isolation and/or quarantine. [public health/public safety]
- ☐ Ensure that legal counsel has reviewed draft legal orders, motions, and templates to quarantine facilities and to credential ingress and egress into such facilities. [public health/public safety/emergency management]
- ☐ Ensure that legal counsel has reviewed the feasibility of using faith-based organizations to assist or provide services to persons in isolation and quarantine. [public health]
- ☐ Ensure that public health officials have reviewed the availability of workers' compensation and/or other forms of financial support for persons unable to return to work because of an isolation/quarantine order. [public health]
- ☐ Ensure that legal counsel has considered whether the health department should issue documents designed to assist with reintegration of persons subject to isolation/quarantine order (e.g., letter to employer or school explaining that patient is no longer infectious). [public health]
- ☐ Ensure that legal counsel has reviewed agreements relating to overtime and/or flexibility of hours for staff. [public health/hospitals/public safety/emergency management]
- ☐ Ensure that legal counsel has a clear understanding of legal authorities relevant to environmental remediation of buildings. [public health/hospitals/emergency management]

## Partnerships/Outreach

- ☐ Assemble a legal preparedness task force with representation from public health, public safety, hospitals, emergency management, judiciary, and other relevant individuals and/or organizations at various levels of authority (federal, state, tribal, local, cross-border). [public health/public safety/hospitals/emergency management/judiciary]
- ☐ Establish procedures for enforcement of isolation/quarantine orders. [public health/public safety]
- ☐ Provide public safety personnel with educational materials relating to pandemic influenza and have a clear understanding for how to enforce an isolation/quarantine order. [public health/public safety]
- ☐ Ensure that procedures or protocols exist between hospitals and public health to manage a possible or known pandemic influenza case-patient who attempts to leave the hospital against medical advice. [public health/hospitals/public safety]
- ☐ Where applicable, draft memoranda of agreement (MOA) or understanding (MOU) to allow for the loaning of facilities or other services necessary to implement a quarantine and/or isolation order for persons who cannot be isolated at home (e.g., travelers, homeless populations). [public health/hospitals/emergency management]
- ☐ Ensure that judges and attorneys in the area, through local bar organizations or other entities, have received educational materials, training, or information related to SARS and the potential use of isolation/quarantine to interrupt disease transmission. [public health/judiciary]
- ☐ Ensure that legal counsel has reviewed and/or drafted data sharing/data use/confidentiality agreements related to sharing of confidential patient medical information between public health and other partners. [public health/hospitals/public safety/emergency management]

## Due Process Considerations

- ☐ Draft legal orders and templates using terms such as "quarantine," "isolation," and "detention" consistently. [public health/judiciary]
- ☐ Ensure that legal counsel has reviewed all draft isolation/quarantine orders and forms, as well as applicable administrative hearing procedures, to ensure concurrence with basic elements of due process (e.g., adequate notice, opportunity to contest, administrative determination). [public health/judiciary]
- ☐ Ensure that procedures or protocols exist to ensure that persons subject to an isolation/quarantine order have access to legal counsel, if desired (e.g., list of attorneys willing to provide services at little or no cost). [public health/judiciary]
- ☐ Ensure that legal counsel has analyzed procedures needed to satisfy due process in different isolation/quarantine scenarios (e.g., "voluntary" home isolation, isolation in a guarded facility, exclusion from certain public activities). [public health/judiciary]
- ☐ Where applicable, ensure that public health officials have worked with the local court system to develop a 24 hours a day, 7 days a week "on call" list of judges or hearing officers to review emergency requests for isolation/quarantine. [public health/judiciary]
- ☐ Ensure that public health officials have worked with the local court system to develop a plan for hearing cases and/or appeals for persons subject to isolation/quarantine orders (e.g., participation via telephone, video conference). [public health/judiciary]

## Legal Resources and Statutes

- ☐ Ensure that legal counsel has reviewed and has a clear understanding of the legal resources and tools relevant to a community's public health response. [public health/judiciary/emergency management]

Such resources and tools include:

- Draft Model State Emergency Health Powers Act  
[www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf](http://www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf)



- Emergency Management Assistance Compact (model agreement)  
<http://www.emacweb.org/?13>
- Emergency Management Assistance Compact (as implemented in a state or jurisdiction)
- Memorandum of Understanding for Establishment of Local Public Health Mutual Aid and Assistance System:  
[www.publichealthlaw.net/Resources/ResourcesPDFs/MOU.pdf](http://www.publichealthlaw.net/Resources/ResourcesPDFs/MOU.pdf)
- American Bar Association Draft Checklist for State and Local Government Attorneys to Prepare for Possible Disasters  
<http://www.publichealthlaw.net/Resources/BTlaw.htm>
- Legal Authorities for Isolation and Quarantine  
<http://www.cdc.gov/ncidod/sars/legal.htm>
- Quarantine and Isolation: Lessons Learned from SARS  
<http://www.louisville.edu/medschool/ibhpl/images/pdf/SARS%20REPORT.pdf>
- Checklists on Legal Preparedness for Bioterrorism and other Public Health Emergencies  
<http://www.publichealthlaw.net/Resources/BTlaw.htm>
- Legal Materials Related to Public Health Legal Preparedness  
[http://www2a.cdc.gov/phlp/sub\\_menu.asp](http://www2a.cdc.gov/phlp/sub_menu.asp)

Additional materials and resources may be posted at <http://www.cdc.gov/phlp/index.htm>

- ☐ Distribute draft letters or fact sheets to hospitals and other healthcare providers describing permissible uses and disclosures of health information for public health purposes under the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) ([www.hhs.gov/ocr/hipaa/](http://www.hhs.gov/ocr/hipaa/)). [public health/hospitals]
- ☐ Where applicable, ensure that legal counsel understands procedures for declaring a public health emergency (at various levels of government) and consequences of such a declaration. [public health/public safety/emergency management]
- ☐ Ensure that legal counsel is familiar with the requirements of the Emergency Medical Treatment and Active Labor Act (EMTALA) ([www.aaem.org/emtala/index.shtml](http://www.aaem.org/emtala/index.shtml)) and has determined if such requirements have been incorporated into public health and hospital planning for pandemic influenza. [public health/hospitals]
- ☐ Ensure that legal counsel has reviewed hospital screening and admission procedures for potential pandemic influenza patients (e.g., establishment of evaluation clinics for persons with influenza-like symptoms) for compliance with EMTALA. [public health/hospitals]
- ☐ Ensure that legal counsel has reviewed potential EMTALA implications of a community-wide EMS protocol for transport of pandemic influenza patients (e.g., protocol requiring transport of pandemic influenza patients to a hospital or facility other than the hospital that owns the ambulance). [public health/hospitals/emergency management]

### Legal Liability and Immunity

- ☐ Ensure that legal counsel has reviewed the potential legal liability of implementing "working" quarantine for essential service personnel. [public health/hospitals]
- ☐ Ensure that legal counsel has reviewed the potential legal liability of housing pandemic influenza patients in home isolation with non-exposed residents subject to infection control precautions. [public health]
- ☐ Ensure that legal counsel has reviewed liability/immunity for volunteers providing assistance or services to persons in isolation/quarantine. [public health/emergency management]
- ☐ Ensure that legal counsel has reviewed hospital employment policies on emergency licensure and/or employment of retired or non-medical personnel or personnel from other medical departments or hospitals. [public health/hospitals]

## **APPENDIX 2. FACT SHEET: PRACTICAL STEPS FOR LEGAL PREPAREDNESS**

### **Step 1: Know your legislation**

State and local public health officers need to be familiar with the legal requirements in their jurisdictions regarding isolation of infectious persons and quarantine of exposed persons. Although most states have laws to compel isolation and/or quarantine, procedures may vary widely from jurisdiction to jurisdiction. Key persons, such as legal counsel, judges, and policymakers, should be identified and made part of your jurisdiction's planning for pandemic influenza.

HHS has statutory authority, which has been delegated to CDC, to quarantine or isolate individuals who have been exposed to or infected with pandemic influenza. President Bush added pandemic influenza to the list of quarantineable diseases by Executive Order 13375 on April 1, 2005.

### **Step 2: Plan "due process"**

Procedural due process is implicated when the government seeks to deprive an individual of "liberty" interests within the meaning of the Due Process Clause of the Fifth or Fourteenth Amendment to the U.S. Constitution. Many states, through statute or regulation, have established specific administrative and judicial schemes for affording due process to a person subject to a quarantine and/or isolation order. Schemes in other jurisdictions may not directly address this issue.

Although due process is a flexible concept and calls for procedural protections as the particular situation demands, the basic elements of due process include: adequate notice (typically through written order) of the action the agency seeks to compel; right to be heard (typically through the right to present evidence and witnesses and to contest the government's evidence and witnesses); access to legal counsel; and a final administrative decision that is subject to review in a court of law. These due process protections should not impede the immediate isolation or quarantine of an individual for valid public health reasons in an emergency situation.

### **Step 3: Draft key documents in advance**

State and local public health officers should consider drafting key documents in advance of an emergency. These template documents can be critical time savers in an emergency. Documents that jurisdictions should consider preparing in advance include: draft quarantine and/or isolation orders; supporting declarations and/or affidavits by public health and/or medical personnel; and an explanation of the jurisdiction's due process procedures for persons subject to an isolation/quarantine order. Examples of documents created by other jurisdictions are found at: <http://www.cdc.gov/phlp/index.htm>

### **Step 4: Contact other jurisdictions**

It is possible for federal, state, tribal, and local health authorities simultaneously to have separate but concurrent legal quarantine power in a particular situation (e.g., an arriving aircraft at a large city airport). Furthermore, public health officials at the federal, state, tribal, and local level may occasionally seek the assistance of their respective counterparts, e.g., law enforcement, to assist in the enforcement of a public health order. State and local public health officers should therefore be familiar with the roles and responsibilities of other jurisdictions: vertically (local, state, tribal, federal), horizontally (public health, law enforcement, emergency management, and health care), and in geographical clusters (overlapping state/local neighbors).

### **Step 5: Engage the courts in advance**

Some jurisdictions may rely on older public health statutes that have not been amended in over half a century, while other jurisdictions may have recently revised their legal authorities to respond to bioterrorism or other public health emergencies. Judges who may be called upon to review a public health order may not be familiar with the state or local health authority's

broad public health powers. During the 2003 SARS outbreak in Toronto, Canada, for example, many judges were unaware of the health officer's broad ex parte authority to compel isolation/quarantine under rarely used laws.

### **Step 6: Anticipate practical problems**

State and local public health officers need to be prepared for the practical problems that may arise in affording adequate due process protections to persons subject to isolation and/or quarantine orders. Such problems may include how to arrange for the appearance and representation of persons in quarantine (e.g., video conference or other remote means); how to serve an isolation/quarantine order (likely through law enforcement) and other procedures to advise persons of their legal rights; and isolation arrangements for transient or homeless populations.

### **Step 7: Communication**

Communication planning is vital not only for an effective public health response but also for an effective legal response to a public health emergency. Public health agency counsel should be aware of media training available to other public health officers. During the SARS and monkeypox outbreaks, CDC, through the Public Health Law Program (<http://www.cdc.gov/phlp/index.htm>), established telephone conferences for public health legal counsel to share experiences and engage in peer-to-peer consultations. Efforts are now underway to develop materials to assist state and local public health departments in conducting further outreach on emergency public health issues to the legal community through local bar associations.





# supplement 1 pandemic influenza surveillance

## TABLE OF CONTENTS

|                                                                                                                                                                    |       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|
| SUMMARY OF PUBLIC HEALTH ROLES AND RESPONSIBILITIES IN PANDEMIC INFLUENZA SURVEILLANCE.....                                                                        | S1-2  |
| S1-I. RATIONALE .....                                                                                                                                              | S1-3  |
| S1-II. OVERVIEW .....                                                                                                                                              | S1-3  |
| S1-III. RECOMMENDATIONS FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS.....                                                                                      | S1-3  |
| A. Virologic surveillance during interpandemic influenza seasons .....                                                                                             | S1-4  |
| B. Disease surveillance during interpandemic influenza seasons.....                                                                                                | S1-4  |
| 1. National influenza surveillance system .....                                                                                                                    | S1-4  |
| a) Outpatient surveillance.....                                                                                                                                    | S1-4  |
| b) Hospital surveillance.....                                                                                                                                      | S1-4  |
| c) Mortality surveillance.....                                                                                                                                     | S1-4  |
| d) State-level assessments.....                                                                                                                                    | S1-4  |
| 2. Influenza surveillance coordinators .....                                                                                                                       | S1-5  |
| C. Surveillance for novel strains of influenza during the Pandemic Alert Period .....                                                                              | S1-5  |
| 1. Monitoring for novel strains of influenza .....                                                                                                                 | S1-5  |
| 2. Reporting novel strains of influenza .....                                                                                                                      | S1-5  |
| D. Veterinary surveillance .....                                                                                                                                   | S1-6  |
| E. Preparedness planning for virologic and disease surveillance during a pandemic .....                                                                            | S1-6  |
| 1. Virologic surveillance .....                                                                                                                                    | S1-6  |
| 2. Outpatient surveillance .....                                                                                                                                   | S1-7  |
| 3. Hospitalization surveillance .....                                                                                                                              | S1-7  |
| 4. Mortality surveillance .....                                                                                                                                    | S1-8  |
| 5. State influenza activity assessments.....                                                                                                                       | S1-8  |
| S1-IV. RECOMMENDATIONS FOR THE PANDEMIC PERIOD .....                                                                                                               | S1-8  |
| A. Enhanced surveillance.....                                                                                                                                      | S1-9  |
| B. Scaled-back surveillance.....                                                                                                                                   | S1-9  |
| Table 1. Components of the National Influenza Surveillance System.....                                                                                             | S1-10 |
| Appendix 1. Types of Influenza Surveillance .....                                                                                                                  | S1-11 |
| Appendix 2. Interim Recommendations: Enhanced U.S. Surveillance and Diagnostic Evaluation to Identify Cases of Human Infection with Avian Influenza A (H5N1) ..... | S1-14 |
| Appendix 3. CDC Human Influenza A (H5) Case Screening and Report Form .....                                                                                        | S1-15 |

## **SUMMARY OF PUBLIC HEALTH ROLES AND RESPONSIBILITIES IN PANDEMIC INFLUENZA SURVEILLANCE**

### **INTERPANDEMIC AND PANDEMIC ALERT PERIODS**

#### **State and local responsibilities:**

- Continue to employ state influenza surveillance coordinators to oversee improvements in influenza surveillance (e.g., virologic, outpatient, hospitalization, and mortality surveillance).
- Conduct influenza surveillance year round, where possible.
- Implement enhanced surveillance for detection of the first U.S. cases of novel virus infection.

#### **State and large local public health laboratory responsibilities:**

- Isolate and subtype influenza viruses year round.
- Improve capacity for rapid identification of unusual influenza strains (see also [Supplement 2](#)).

#### **HHS responsibilities:**

- Coordinate and maintain all components of the National Influenza Surveillance System (Table 1).
- Help identify and characterize influenza strains collected by the U.S. WHO Collaborating Laboratory Network.
- Assist USDA, as requested, in monitoring new influenza strains in poultry and swine.
- Work with state and local partners to:
  - Implement enhancements to the National Influenza Surveillance System.
  - Explore options for additional enhancements to improve pandemic surveillance.

### **PANDEMIC PERIOD**

If an influenza pandemic begins in the United States or another country:

#### **State and local responsibilities:**

- Implement enhanced surveillance for detection of the first cases.
- Enhance all influenza surveillance components (virologic, outpatient, hospitalization, and mortality).
- Communicate to all partners the heightened need for timely and complete surveillance data.

#### **HHS responsibilities:**

- Provide technical support, as requested, to ministries of health and WHO to track the pandemic virus and gather epidemiologic data on risk factors for infection or severe illness.
- Issue updated case definitions and guidance for laboratory testing and enhanced surveillance.
- Assist state and local health departments, as requested.
- Analyze influenza surveillance data on a regular and timely basis.



## S1-I. RATIONALE

Pandemic influenza surveillance includes surveillance for influenza viruses (virologic surveillance) and surveillance for influenza-associated illness and deaths (disease surveillance).

The goals of virologic surveillance are to:

- Rapidly detect the introduction and early cases of a pandemic influenza virus in the United States.
- Track the virus' introduction into local areas.
- Monitor changes in the pandemic virus, including development of antiviral resistance.

The goals of disease surveillance are to:

- Serve as an early warning system to detect increases in influenza-like illness (ILI) in the community.
- Monitor the pandemic's impact on health (e.g., by tracking outpatient visits, hospitalizations, and deaths).
- Track trends in influenza disease activity and identify populations that are severely affected.

Virologic and disease surveillance data—supplemented by data from outbreak investigations and special studies—can help decision-makers identify effective control strategies and re-evaluate recommended priority groups for vaccination and antiviral therapy. They can also facilitate efforts to mathematically model disease spread during a pandemic. The national influenza surveillance system, which monitors seasonal influenza, will provide the virologic and disease surveillance data needed to guide response efforts during a pandemic ([www.cdc.gov/flu/weekly/fluactivity.htm](http://www.cdc.gov/flu/weekly/fluactivity.htm); Table 1). When a pandemic begins, some enhancements might be instituted to improve geographic and demographic coverage and increase the amount of detail captured by particular components of the national influenza surveillance system.

## S1-II. OVERVIEW

**Supplement 1** provides recommendations to state and local partners on surveillance for influenza viruses and on disease surveillance to monitor the health impact of influenza. The recommendations for the Interpandemic and Pandemic Alert Periods focus on disease surveillance during interpandemic influenza seasons, as well as on surveillance for human cases of infection with avian influenza A (H5N1) or other novel strains of influenza. They also address preparedness planning for enhanced disease surveillance during a pandemic. The recommendations for the Pandemic Period focus on surveillance activities that will be undertaken if a pandemic virus is reported outside the United States or if a pandemic virus emerges in or enters the United States.

Outbreak investigations and special studies (e.g., to address questions about viral transmission or the clinical course of disease) are described in Part 1. Efforts to monitor the effectiveness and safety of vaccines and antiviral drugs are addressed in **Supplement 6** and **Supplement 7**.

The U.S. Department of Agriculture (USDA), through its Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) program, works with the states and the agricultural industry to conduct influenza surveillance in domestic animals. USDA also monitors wild avian populations for highly pathogenic avian influenza (HPAI) and other diseases of concern through the APHIS Wildlife Services program. Active and passive surveillance for influenza A viruses in poultry in the United States have increased substantially since the outbreak of HPAI in Pennsylvania and surrounding states in 1983 and 1984.

## S1-III. RECOMMENDATIONS FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS

CDC maintains and coordinates a national influenza surveillance system that identifies circulating influenza viruses and monitors disease activity during interpandemic influenza seasons. The seven components of the national influenza surveillance system—whose participants include healthcare providers, vital statistics offices, and local and state health departments and

public health laboratories—are listed in Table 1 and described in detail in Appendix 1. Components address virologic surveillance to determine when, where, and which influenza viruses are circulating, details of the various types of disease surveillance, and an overall state-level assessment of influenza activity.

## **A. Virologic surveillance during interpandemic influenza seasons**

Public health goals for routine surveillance of influenza viruses are to identify and characterize circulating strains to inform annual vaccine formulation and to identify and characterize strains with pandemic potential. State and local public health laboratories, Department of Defense (DOD) laboratories, and clinical laboratories (including hospital and private commercial laboratories) should continue to participate in surveillance for influenza viruses through the U.S.-based collaborating laboratories of the World Health Organization (WHO) Global Influenza Surveillance Network and the National Respiratory and Enteric Virus Surveillance System (NREVSS) (see **Supplement 2**). The aim of the network of WHO and NREVSS laboratories is to monitor influenza trends and compare seasonal differences, rather than to record all influenza tests performed in the United States. Network enhancements that might be useful during the Pandemic Period are discussed below (see S1-III.E).

## **B. Disease surveillance during interpandemic influenza seasons**

### **1. National influenza surveillance system**

The public health goals of influenza disease surveillance are to serve as an early warning system and to detect increases in ILI at the local level, to monitor the impact of influenza on health (e.g., by tracking outpatient visits, hospitalizations, and deaths), and to track trends in influenza disease activity and identify populations that are severely affected. During the Interpandemic Period, these goals are accomplished through the components of the national influenza surveillance system (Table 1). Public health and healthcare partners should continue to participate in these components of the national influenza surveillance system, which address the following types of disease surveillance.

#### **a) Outpatient surveillance**

- Sentinel Provider Network (SPN). Approximately 2,300 healthcare providers nationwide report the number of weekly outpatient visits for ILI and submit specimens from a small subset of patients to state public health laboratories for influenza virus testing.

#### **b) Hospital surveillance**

- Emerging Infections Program (EIP) influenza project. Laboratory-confirmed influenza-associated hospitalizations of children aged <18 years are monitored in 11 communities and reported to CDC on a bi-weekly basis.
- New Vaccine Surveillance Network (NVSN). Laboratory-confirmed influenza-associated hospitalizations of children aged <5 years are monitored in three communities and reported to CDC on a bi-weekly basis.

#### **c) Mortality surveillance**

- 122 Cities Mortality Reporting System. Vital statistics offices in 122 U.S. cities report pneumonia and influenza (P&I)-related deaths on a weekly basis.
- National Notifiable Disease Surveillance System (NNDSS) pediatric deaths. State health departments report influenza-associated pediatric deaths to CDC.

#### **d) State-level assessments**

- State and territorial epidemiologists' reports. Health departments provide weekly reports on the overall level of influenza activity in their states/territories.

It is not possible to provide an absolute case count for influenza or to determine population-based rates of infection or illness on a national level because many infected persons are asymptomatic or experience only mild illness and do not seek medical care. Also, laboratory testing is rare in less severe cases, and testing late in the course of illness (e.g., in cases with severe complications) can yield false-negative results because the patient is no longer shedding virus. Nevertheless, weekly data on outpatient visits for ILI, hospitalizations, and deaths allow CDC to monitor regional disease trends and to compare the timing and intensity of the current season to that of previous seasons.

Influenza surveillance has traditionally been conducted from October through May. In recent years, however, increasing numbers of healthcare providers, laboratories, and health departments have conducted influenza surveillance year-round. This enhancement is an important part of surveillance for novel strains of influenza.

## 2. Influenza surveillance coordinators

Currently, health departments in all 50 states—as well as in Chicago, New York City, and Washington, DC—have dedicated influenza surveillance coordinators who work at least part-time on influenza surveillance. The roles of the coordinators are to:

- Maintain the current influenza Sentinel Provider Network
- Oversee the surveillance enhancements described below
- Promote year-round influenza surveillance
- Remain in close contact with the CDC Influenza Branch
- Maintain working relationships with the state public health laboratory

## C. Surveillance for novel strains of influenza during the Pandemic Alert Period

### 1. Monitoring for novel strains of influenza

During the Pandemic Alert Period, CDC will issue recommendations for enhanced surveillance to identify patients at increased risk for infection with a novel virus. Novel influenza strains might include avian influenza viruses that can infect humans, other animal influenza viruses (such as swine influenza viruses) that can infect humans, or new or re-emergent human influenza strains that cause cases or clusters of human disease.

The specific recommendations will depend on the epidemiology of the virus and the clinical characteristics of the human cases as they are known at the time, and will most likely focus on severely ill, hospitalized, or ambulatory patients who meet certain epidemiologic and clinical criteria. For example, since February 2004, CDC has recommended enhanced surveillance to identify patients potentially infected with avian influenza A (H5N1). The current recommendations are summarized in Appendix 2.

State and local health departments will be notified of current recommendations via the Health Alert Network (HAN) and Epi-X. Health departments should distribute the recommendations to healthcare providers and will be responsible for receiving initial reports of potential cases in their jurisdictions.

Once a novel strain detected abroad exhibits sustained human-to-human transmission (WHO Phase 6), recommendations for further intensified virologic and disease surveillance will be issued and might include recommendations for stepped-up disease surveillance at U.S. ports of entry (see Supplement 8).

### 2. Reporting novel strains of influenza

- Clinicians should immediately contact the health department when they suspect a human case of infection with an avian or animal strain of influenza or with any other novel human influenza strain. Clinical algorithms for managing patients with possible novel influenza infection are provided in Supplement 5.

- State and local health departments should in turn immediately report to CDC any influenza cases that:
  - Test positive for a novel influenza subtype, *or*
  - Meet the enhanced surveillance case definition in effect at that time, *and*
  - Cannot be subtyped in the state public health laboratory because appropriate reagents or biocontainment equipment is not available (see **Supplement 2**).

Reference testing guidelines for potential pandemic strains of influenza are provided in **Supplement 2**.

- Health departments should call the CDC Emergency Response Hotline (770-488-7100) to report a suspected case of infection with avian influenza A (H5N1) or any other novel influenza virus. This number is available 24 hours a day, 7 days a week. Hotline staff will notify a member of the Influenza Branch who will contact the health department to answer questions and provide guidance.
- Following the initial telephone report, health department officials should complete a CDC case screening and report form (obtained from the Hotline or from Epi-X) that includes the CDC case ID number provided during the phone consultation. CDC staff will assist local and state health departments, as needed, in completing the form, which should be faxed to CDC at 888-232-1322 with a cover sheet that says: "ATTN: Influenza case reporting." The case screening and report form used to report suspected cases of human infection with influenza A (H5N1) is provided in Appendix 3.
- If infection with a novel influenza virus is confirmed, states may request CDC assistance with a case investigation to identify the source of infection and determine the course of illness. CDC will assist the state health department in monitoring the close contacts of the ill person.

## D. Veterinary surveillance

In the United States, surveillance for avian influenza is conducted by states, the poultry industry, and the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) (Appendix 4). Diagnostic testing is performed by state and industry laboratories, with confirmatory testing by USDA/APHIS Veterinary Services at the National Veterinary Services Laboratories in Ames, Iowa.

CDC and state health departments will continue to assist USDA and state veterinary diagnostic laboratories, as requested, in monitoring influenza strains among poultry and swine. Recent instances of human infection with avian influenza viruses are described in **Supplement 2**, Box 2.

## E. Preparedness planning for virologic and disease surveillance during a pandemic

Surveillance enhancements that will be needed during a pandemic should be developed during the Interpandemic and Pandemic Alert Periods so that baseline data for interpreting information gathered during the pandemic will be available and staff will have experience and familiarity with new methodologies.

### 1. Virologic surveillance

During an influenza pandemic, the volume of requests for laboratory testing is expected to increase dramatically. To meet these demands, laboratories should become proficient in methods that allow efficient testing of large numbers of specimens at a lower biosafety level than BSL 3 with enhancements—which is required for viral culture of avian influenza A (H5N1) viruses. To ensure adequate virologic surveillance during a pandemic, state public health laboratories should:

- Be equipped and trained to use RT-PCR for routine influenza testing and to detect novel influenza viruses by RT-PCR or by viral culture, using proper safety precautions
- Maintain reagents and supplies to allow influenza virus testing year-round

- Develop surge capacity to handle increased testing and reporting during a pandemic
- Assist CDC, if requested, in developing an electronic mechanism for reporting influenza testing and results

CDC is currently working with state and local partners to evaluate the utility and feasibility of reporting patient-level data (including zip code and/or county of residence) through an electronic mechanism other than the Public Health Laboratory Information System (PHLIS). Such a system would allow daily (rather than weekly) reporting during a pandemic and analysis of virus spread at the county or health district level. During a pandemic—as the burden of disease increases and state and local health departments face multiple, competing demands—it might be necessary to adjust surveillance strategies and reassess the need for frequent (or daily) reporting.

## 2. Outpatient surveillance

Surveillance for outpatient visits for ILI is conducted via the SPN, a collaborative effort among state health departments, healthcare providers, and CDC. State health departments recruit and maintain a local network of healthcare providers who report weekly the total number of patient visits and number of patients with ILI. SPN members may also send specimens from a subset of patients with ILI to the state public health laboratory for diagnostic testing at no cost. CDC develops and maintains reporting materials and systems, serves as a data repository, and provides feedback to the states. Each state should have at least one sentinel provider per 250,000 persons (or a minimum of 10 providers in states with smaller populations) that reports year-round.

CDC is exploring options for enhancing or supplementing ILI outpatient surveillance at the national, regional, and state levels, given that healthcare providers might not be able to report ILI in a timely manner when overwhelmed with patients during an emergency. Existing electronic data sources that might increase the geographic completeness, frequency of reporting, and sustainability of ILI data include:

- BioSense system, which includes ICD-9-coded outpatient visits at DOD ambulatory-care centers and Department of Veterans Affairs outpatient clinics. Studies are underway to determine if BioSense data can be combined with SPN data in a useful way and if they can be reported and analyzed daily.
- Existing emergency department “chief complaint” monitoring systems used by several states. Studies are underway to determine if these data can be added to SPN data and if they can be reported and analyzed daily.

CDC is also working with state and local partners to evaluate the need for and utility and feasibility of expanding SPN to allow analysis of ILI data at the county or health-district level and to provide data that are updated daily rather than weekly. Options for improving the analysis of ILI data include the use of:

- Outbreak detection algorithms that might identify aberrant increases in ILI activity at the individual provider/site level
- Daily analyses of SPN data for use by CDC and state health departments. CDC does not plan to ask sentinel providers to report more than once a week.

Some states are considering the use of systematic phone surveys to supplement SPN data during a pandemic by providing estimates of local cases and affected households. CDC will explore the utility and feasibility of conducting this type of survey on a national level.

## 3. Hospitalization surveillance

During a pandemic, hospitalization data will be needed on a frequent basis in all parts of the country to monitor disease severity and determine the most severely affected age groups. At present, however, surveillance for hospitalizations associated with influenza is limited to the collection of data on pediatric hospitalizations in 12 large metropolitan areas (see Table 1). In January 2006, the EIP influenza project will be expanded to include laboratory-confirmed influenza-associated hospitalizations of adults as well as children.

CDC is exploring options for expanding hospitalization surveillance to obtain data from all age groups in all parts of the country and obtaining more detailed information from a small number of sites. Some options under review include:

- Continuing to work with the Council of State and Territorial Epidemiologists (CSTE) to make laboratory-confirmed influenza-associated hospitalizations nationally notifiable. A position statement to add influenza infection requiring hospitalization to the list of nationally notifiable diseases was rejected by CSTE members in June 2005 but will be resubmitted in June 2006.
- Obtaining timely hospital discharge data to estimate the number of influenza-associated hospitalizations across the country
- Adding a hospitalization surveillance component to the national BioSense system
- Developing protocols for active population-based hospitalization surveillance, including specimen collection and virologic testing from a subset of hospitalized patients in all age groups in a limited number of sites
- Developing protocols for reporting the number of influenza-associated hospitalizations

#### **4. Mortality surveillance**

The collection of mortality data can also help health departments monitor the severity of a pandemic and determine which age groups and areas are most affected. Although pediatric deaths due to laboratory-confirmed influenza are nationally notifiable (as of October 2004), timely data on influenza deaths in other age groups are limited to information provided by the 122 Cities Mortality Reporting System, which provides weekly reports of the total number of death certificates that list P&I as a cause of death and the total number of death certificates filed (Table 1). Although the National Center for Health Statistics (NCHS) also collects mortality data, these data are not available until 2–3 years after each influenza season.

During a pandemic, state and local policy-makers and public health officials will likely ask health departments to provide mortality data to guide decision-making on control and response measures. In addition, CDC will request mortality data from each state to help guide national response measures. To help ensure uniform data collection across jurisdictions, CDC will provide case definitions and reporting procedures via HAN and Epi-X.

CDC is also investigating the feasibility of obtaining mortality data through the Electronic Death Registration (EDR) Project (<http://www.naphsis.org/projects/index.asp?bid=374>) and the validity of estimating national mortality based on data from the 122 Cities Mortality Reporting System. State-specific mortality cannot be estimated from data provided by the 122 Cities system.

#### **5. State influenza activity assessments**

During the Interpandemic Period, state health departments provide weekly assessments of the overall level of influenza activity (i.e., none, sporadic, local, regional, widespread) in the state. These assessments are used to compare the extent of influenza activity from state to state, and are the only state-level influenza surveillance data that CDC makes publicly available during interpandemic influenza seasons. The state influenza activity assessments are used to generate the influenza activity map, which is the most frequently referenced component of national influenza surveillance (see [www.cdc.gov/flu/weekly/usmap.htm](http://www.cdc.gov/flu/weekly/usmap.htm)). During a pandemic, CDC will recommend that these assessments be made year-round, rather than only October through May.

### **S1-IV. RECOMMENDATIONS FOR THE PANDEMIC PERIOD**

During a pandemic, more detailed information on age-specific, population-based rates of severe disease and patient outcomes will be needed than can be provided through routine national surveillance. This information will be obtained through enhanced national surveillance and carefully designed studies in a limited number of sites. These data will provide information to guide response and policy development during a pandemic. Outbreak investigations and special studies are described in Part 1.



## A. Enhanced surveillance

During an influenza pandemic, CDC will use data from the U.S. collaborating laboratories of the WHO Global Influenza Surveillance Network and the NREVSS to detect the introduction and early cases of a pandemic influenza virus in the United States, track the virus' introduction into local areas, and monitor changes in the pandemic virus, including development of antiviral resistance. States should conduct the following activities:

- Distribute to healthcare providers the current CDC recommendations for enhanced surveillance for the detection of the first cases of the pandemic virus in their jurisdictions.
- Facilitate the collection and testing of appropriate specimens as recommended for early detection of pandemic virus at the local level.
- Increase testing and the frequency of reporting of virologic data. The most intense testing will be necessary during the early stages of a pandemic, when detecting the introduction of the virus into a state or community is the primary goal.
- Once the virus has been identified throughout the state, the level of testing can be decreased to a level more like that of a non-pandemic influenza season. State health officials can determine the level of testing for their jurisdictions.
- As part of the effort to monitor antigenic and genetic changes and changes in antiviral resistance patterns in the pandemic virus, state public health laboratories should forward a subset of virus isolates to CDC. CDC will advise states on the number of and clinical criteria for these isolates. **Supplement 2** contains additional information on monitoring for antiviral resistance.

During an influenza pandemic, CDC will use data from SPN, hospitalization surveillance, state and territorial epidemiologists' assessments, the 122 Cities Mortality Reporting System, NNDSS, and other data systems to:

- Monitor the pandemic's impact on health
- Track trends in influenza disease activity and identify populations that are severely affected
- Serve as an early warning system to detect increases in ILI in the community

State health departments should:

- Communicate to all partners the heightened need for timely and complete surveillance data.
- Ensure that all sentinel provider surveillance sites are reporting weekly, regardless of the time of year.
- Ensure that EIP and NVSN hospitalization surveillance is active.
- Report state influenza activity level in a timely manner.
- Facilitate timely reporting of 122 Cities Mortality Reports and pediatric deaths.
- Implement state and local collection of influenza-associated mortality data and reporting of statewide mortality data to CDC, following CDC guidelines for uniform data collection and reporting.

## B. Scaled-back surveillance

Enhanced surveillance will be conducted during the introduction, initial spread, and first waves of a pandemic. Over time, as more persons are exposed, the pandemic strain is likely to become a routinely circulating influenza A subtype. When that happens, the activities of the national influenza surveillance system will revert to the frequency and intensity typically seen during interpandemic influenza seasons. The return to interpandemic surveillance will occur as soon as feasible, and the change will be communicated to all surveillance partners.



**TABLE 1. COMPONENTS OF THE NATIONAL INFLUENZA SURVEILLANCE SYSTEM**

| Activity                                                                                                                                                                                                             | Surveillance type       | Description                                                                                                                                                                                                                                                                                                                           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| U.S. collaborating laboratories of the: <ul style="list-style-type: none"> <li>• WHO Global Influenza Surveillance Network</li> <li>• National Respiratory and Enteric Virus Surveillance System (NREVSS)</li> </ul> | Virologic surveillance  | Collaborating laboratories report weekly to CDC the number of influenza tests performed and the number of positive results by type, and in some cases, subtype and age group. If non-subtypable viruses or unusual subtypes are detected, the specimens are sent to the state public health laboratory or to CDC for further testing. |
| Sentinel Provider Network (SPN)                                                                                                                                                                                      | Outpatient surveillance | Approximately 2,300 healthcare providers monitor outpatient visits for ILI (fever >100°F or 37.8°C AND sore throat and/or cough in the absence of a known cause other than influenza). Specimens from a small subset of patients are submitted to state public health laboratories for influenza virus testing.                       |
| Emerging Infections Program (EIP) influenza project                                                                                                                                                                  | Hospital surveillance   | Eleven EIP sites report to CDC cases of laboratory-confirmed influenza-related hospitalizations in children aged <18 years on a bi-weekly basis.                                                                                                                                                                                      |
| New Vaccine Surveillance Network (NVSN) pediatric hospitalizations                                                                                                                                                   | Hospital surveillance   | NVSN enrolls a subset of patients aged <5 years who are hospitalized with fever or respiratory symptoms. Nose and throat swabs are obtained and tested for influenza by viral culture and RT-PCR. The rate of laboratory-confirmed influenza-related hospitalizations is reported to CDC on a bi-weekly basis.                        |
| 122 Cities Mortality Reporting System                                                                                                                                                                                | Mortality surveillance  | Municipal vital records offices transmit weekly data to CDC on the total number of death certificates filed and the number with pneumonia and/or influenza listed as a cause of death.                                                                                                                                                |
| National Notifiable Disease Surveillance System (NNDSS) influenza-associated pediatric mortality                                                                                                                     | Mortality surveillance  | Participating state health departments report to CDC all laboratory-confirmed influenza-related deaths among children <18 years.                                                                                                                                                                                                      |
| State and territorial epidemiologists' reports                                                                                                                                                                       | State-level assessments | Health departments report on a weekly basis the overall level of influenza activity as none, sporadic, local, regional, or widespread.                                                                                                                                                                                                |

## APPENDIX 1. TYPES OF INFLUENZA SURVEILLANCE

### A. Virologic surveillance

- A network of ~75 WHO collaborating laboratories and ~90 NREVSS collaborating laboratories report the total number of respiratory specimens tested and the number positive for influenza by type, subtype, and age group to CDC each week. (Because ~40 of the NREVSS laboratories are also WHO laboratories, the total number in the WHO/NREVSS network is ~125.) Data from the two networks are combined and analyzed together.
- WHO collaborating laboratory network
  - All 50 state health department laboratories, 4 large county public health laboratories, a DOD reference laboratory, and ~25 tertiary-care hospital and academic center laboratories participate.
  - State and county public health laboratories subtype (i.e., A/H1 vs. A/H3) ~80% of their influenza A isolates.
  - Laboratories report the number of tests performed and results by age group to CDC's Influenza Branch.
  - Approximately 30% of laboratories report specimen-level data electronically using PHLIS, ~40% report aggregate weekly data via the Internet, and ~30% report aggregate weekly data via fax.
- NREVSS collaborating laboratory network
  - Primarily hospital laboratories
  - Most do not subtype influenza viruses, and none report age-group data
  - Laboratories report aggregate weekly numbers of tests performed and results to CDC's Respiratory and Enteric Viruses Branch (REVB) by phone or Internet.
- Laboratories test for influenza viruses by viral culture, PCR, or antigen detection.
- Most laboratories maintain the ability to test for influenza year-round.
- Data are available to state health department influenza surveillance coordinators on a password-protected website that is updated once a week during October through May and periodically throughout the summer. National and regional data are made available to all states, and state-specific data (including a laboratory-specific line list) are available to the states from which the data were reported.

### B. Outpatient ILI surveillance (Sentinel Provider Network)

- Network of ~2,300 primary-care providers in all 50 states record the number of outpatients seen for any reason and the number with ILI by age group and report directly to CDC each week.
- ILI is defined as fever ( $>100^{\circ}\text{F}$  or  $37.8^{\circ}\text{C}$ ) AND sore throat and/or cough in the absence of a known cause other than influenza.
- All providers report from October through May, and approximately one third of the regular reporters report year-round.
- The network is a collaborative effort between CDC and state health departments.
  - State health department influenza surveillance coordinators recruit and maintain a network of providers and arrange for testing, free of charge, for a subset of specimens from providers.
  - CDC develops and maintains reporting materials and systems, serves as a data repository, and provides data feedback to the states.
- Providers collect two or three specimens from patients with ILI at the beginning, middle, and end of the season and from any unusual clinical cases, severe cases, outbreak-related cases, and patients with ILI during the summer.
- Providers report to CDC via a password-protected Internet site (75%), fax (13%), or phone (12%).

- Data are available to state health department influenza surveillance coordinators on a password-protected website. Data reported by providers on the Internet are available in real time, and data reported to CDC by fax are updated once each weekday. Regional data are available to all states, whereas state-specific data are available to the states from which the data were reported.

### C. Hospitalization surveillance

- Hospitalizations associated with laboratory-confirmed influenza in children are monitored in 12 metropolitan areas through two surveillance networks that report patient-level data to CDC every 2 weeks.
- Emerging Infections Program (EIP) influenza project. Children aged <18 years are monitored in 11 metropolitan areas from October 1 through April 30; laboratory testing is part of routine patient care. The EIP influenza project will expand to include all age groups in January 2006.
- New Vaccine Surveillance Network (NVSN). A sample of children aged <5 years is monitored in three metropolitan areas (two are EIP influenza project sites) from October 1 through March/April; all sampled children with fever and respiratory symptoms are tested on admission.

### D. Mortality surveillance

- Vital statistics offices in 122 cities covering between one-fourth and one-third of the U.S. population report weekly throughout the year the total number of death certificates filed and the number with pneumonia and/or influenza listed anywhere on the death certificate, by age group. No additional information (e.g., underlying medical condition, demographics) is available. On average, there is a 15-day lag from death to report to CDC.
- Weekly mortality data from the 122 cities are compared to a seasonal baseline calculated using a robust regression procedure run on the previous 5 years of data. If the proportion of P&I deaths for a given week exceeds the baseline value for that week by a statistically significant amount, P&I deaths are said to be above the epidemic threshold, and the proportion of deaths above threshold are considered attributable to influenza.
  - Data from all 122 cities are combined, and the percentage of all P&I deaths are calculated and compared to the expected percentage for that week.
  - Data can be analyzed by age group and geographic region, but interpretation of the data requires the development of a separate baseline for each data subset. It is not valid to compare data from a particular city or region to the national baseline.
- Detailed data (e.g., person-level data including multiple causes of death, underlying medical conditions, demographics) on ~99% of deaths in the United States are available from NCHS, but these data have a time lag of ~2–3 years.
- Pediatric deaths associated with laboratory-confirmed influenza were made nationally notifiable in October 2004. During the 2004–2005 season, the condition was reportable in 13 states; many others instituted voluntary reporting until the legal requirement was passed. CDC receives electronic, patient-level data on these deaths. The timeliness of these data cannot yet be assessed.

### E. State-level influenza activity assessments

State health departments report a weekly assessment of the overall level of influenza activity (none, sporadic, local, regional, or widespread) in the state (see box below). These assessments are used to compare the extent of influenza activity from state to state and represent the only state-level influenza surveillance data that CDC makes publicly available during the interpandemic influenza season.

**TABLE 2. COMPONENTS OF THE NATIONAL INFLUENZA SURVEILLANCE SYSTEM**

| Activity level                                               | ILI activity*/outbreaks                                                                             |            | Laboratory data                                                                                                                                      |
|--------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>No activity</b>                                           | Low                                                                                                 | <b>and</b> | No lab-confirmed cases <sup>†</sup>                                                                                                                  |
| <b>Sporadic</b>                                              | Not increased                                                                                       | <b>and</b> | Isolated lab-confirmed cases                                                                                                                         |
|                                                              | <b>or</b>                                                                                           |            | Lab-confirmed outbreak in one institution <sup>‡</sup>                                                                                               |
| <b>Local</b>                                                 | Not increased                                                                                       |            | Recent (within the past 3 weeks) lab evidence of influenza in region with increased ILI                                                              |
|                                                              | Increased ILI in 1 region <sup>**</sup> ; ILI activity in other regions is not increased            | <b>and</b> | Recent (within the past 3 weeks) lab evidence of influenza in region with the outbreaks; virus activity is no greater than sporadic in other regions |
|                                                              | <b>or</b>                                                                                           |            | Recent (within the past 3 weeks) lab-confirmed influenza in the affected regions                                                                     |
| <b>Regional</b><br>(doesn't apply to states with ≤4 regions) | Increased ILI in ≥2 but less than half of the regions                                               | <b>and</b> | Recent (within the past 3 weeks) lab-confirmed influenza in the affected regions                                                                     |
| <b>Widespread</b>                                            | <b>or</b>                                                                                           |            | Recent (within the past 3 weeks) lab-confirmed influenza in the state.                                                                               |
|                                                              | Institutional outbreaks (ILI or lab confirmed) in ≥2 and less than half of the regions              | <b>and</b> |                                                                                                                                                      |
|                                                              | Increased ILI and/or institutional outbreaks (ILI or lab confirmed) in at least half of the regions |            |                                                                                                                                                      |

\* ILI activity can be assessed using a variety of data sources, including Sentinel providers, school/workplace absenteeism, and other syndromic surveillance systems that monitor influenza-like illness.

<sup>†</sup> Lab-confirmed case = case confirmed by rapid diagnostic test, antigen detection, culture, or PCR. Care should be given when relying on results of point-of-care rapid diagnostic test kits during times when influenza is not circulating widely. The sensitivity and specificity of these tests vary, and the predictive value positive may be low outside of peak influenza activity. Therefore, a state may wish to obtain laboratory confirmation of influenza by testing methods other than point-of-care rapid tests for reporting the first laboratory-confirmed case of influenza of the season.

<sup>‡</sup> Institution = nursing home, hospital, prison, school, etc.

<sup>\*\*</sup> Region = population under surveillance in a defined geographical subdivision of a state. A region could be comprised of one or more counties and would be based on each state's specific circumstances. Depending on the size of the state, the number of regions could range from 2 to approximately 12. The definition of regions would be left to the state, but existing state health districts could be used in many states. Allowing states to define regions would avoid somewhat arbitrary county lines and allow states to establish divisions that make sense based on geographic population clusters. Focusing on regions larger than counties would also improve the likelihood that data needed for estimating activity would be available.

## APPENDIX 2. INTERIM RECOMMENDATIONS: ENHANCED U.S. SURVEILLANCE AND DIAGNOSTIC EVALUATION TO IDENTIFY CASES OF HUMAN INFECTION WITH AVIAN INFLUENZA A (H5N1)

**NOTE:** This guidance pertains to the avian influenza A (H5N1) circulating as of October 2005 CDC will provide updated guidance for avian influenza A (H5N1) or for new situations, as needed, through the Health Alert Network.

Enhanced surveillance efforts by state and local health departments, hospitals, and clinicians are needed to identify patients at increased risk for influenza A (H5N1). Interim recommendations are as follows:

- Testing for avian influenza A (H5N1) is indicated for **hospitalized** patients with:
  - Radiographically confirmed pneumonia, acute respiratory distress syndrome (ARDS), or other severe respiratory illness for which an alternative diagnosis has not been established, **and**
  - History of travel within 10 days of symptom onset to a country with documented avian influenza A (H5N1) infections in poultry and/or humans. (For a regularly updated listing of H5N1-affected countries, see the World Organization for Animal Health [OIE] website at [http://www.oie.int/eng/en\\_index.htm](http://www.oie.int/eng/en_index.htm) and the WHO website at <http://www.who.int/en/>).

**OR**

- Testing for avian influenza A (H5N1) should be considered on a case-by-case basis in consultation with state and local health departments for **hospitalized or ambulatory** patients with:
  - Documented temperature of  $>100.4^{\circ}\text{F}$  ( $>38^{\circ}\text{C}$ ); **and**
  - One or more of the following: cough, sore throat, or shortness of breath; **and**
  - History of contact with poultry (e.g., visited a poultry farm, a household raising poultry, or a bird market) or a known or suspected human case of influenza A (H5N1) in an H5N1-affected country within 10 days prior to onset of symptoms.

**APPENDIX 3. CDC HUMAN INFLUENZA A(H5) CASE SCREENING AND REPORT FORM****Human Influenza A (H5)****Human Influenza A (H5) Domestic Case Screening Form**

CDC Case ID: \_\_\_\_\_

|                                                                                                                                                                                                                                                                                                                                                              |                    |                                                                                                                                                                                                                                                                                                  |              |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| <b>1. Reported By</b>                                                                                                                                                                                                                                                                                                                                        |                    |                                                                                                                                                                                                                                                                                                  |              |
| Date reported to state or local health department: ____ / ____ / ____<br>m m d d y y y y                                                                                                                                                                                                                                                                     |                    | State/ local Assigned Case ID: _____                                                                                                                                                                                                                                                             |              |
| Last Name: _____                                                                                                                                                                                                                                                                                                                                             |                    | First Name: _____                                                                                                                                                                                                                                                                                |              |
| State: _____                                                                                                                                                                                                                                                                                                                                                 | Affiliation: _____ | Email: _____                                                                                                                                                                                                                                                                                     |              |
| Phone 1: _____                                                                                                                                                                                                                                                                                                                                               | Phone 2: _____     | Fax: _____                                                                                                                                                                                                                                                                                       |              |
| <b>2. Patient Information</b>                                                                                                                                                                                                                                                                                                                                |                    |                                                                                                                                                                                                                                                                                                  |              |
| City of Residence: _____                                                                                                                                                                                                                                                                                                                                     |                    | County: _____                                                                                                                                                                                                                                                                                    | State: _____ |
| Age at onset: _____<br><input type="checkbox"/> Year(s)<br><input type="checkbox"/> Month(s)                                                                                                                                                                                                                                                                 |                    | Race: <i>(Choose One)</i><br><input type="checkbox"/> American Indian/Alaska Native<br><input type="checkbox"/> Asian<br><input type="checkbox"/> Black<br><input type="checkbox"/> Native Hawaiian/Other Pacific Islander<br><input type="checkbox"/> White<br><input type="checkbox"/> Unknown |              |
| Sex: <input type="checkbox"/> Male<br><input type="checkbox"/> Female                                                                                                                                                                                                                                                                                        |                    | Ethnicity: <input type="checkbox"/> Non Hispanic<br><input type="checkbox"/> Hispanic                                                                                                                                                                                                            |              |
| <b>3. Optional Patient Information</b>                                                                                                                                                                                                                                                                                                                       |                    |                                                                                                                                                                                                                                                                                                  |              |
| Last Name: _____                                                                                                                                                                                                                                                                                                                                             |                    | First Name: _____                                                                                                                                                                                                                                                                                |              |
| <b>4. Signs and Symptoms</b>                                                                                                                                                                                                                                                                                                                                 |                    |                                                                                                                                                                                                                                                                                                  |              |
| A. Date of symptom onset: ____ / ____ / ____<br>m m d d y y y y                                                                                                                                                                                                                                                                                              |                    |                                                                                                                                                                                                                                                                                                  |              |
| B. What symptoms and signs did the patient have during the course of illness?<br>(check all that apply)                                                                                                                                                                                                                                                      |                    |                                                                                                                                                                                                                                                                                                  |              |
| <input type="checkbox"/> Fever > 38° C (100.4° F) <input type="checkbox"/> Feverish (temperature not taken) <input type="checkbox"/> Conjunctivitis<br><input type="checkbox"/> Cough <input type="checkbox"/> Headache <input type="checkbox"/> Shortness of breath<br><input type="checkbox"/> Sore throat <input type="checkbox"/> Other (specify): _____ |                    |                                                                                                                                                                                                                                                                                                  |              |
| C. Was a chest X-ray or chest CAT scan performed? <input type="checkbox"/> Yes* <input type="checkbox"/> No <input type="checkbox"/> Unknown                                                                                                                                                                                                                 |                    |                                                                                                                                                                                                                                                                                                  |              |
| If yes*, did the patient have radiographic evidence of pneumonia or respiratory distress syndrome (RDS)? <input type="checkbox"/> Yes* <input type="checkbox"/> No <input type="checkbox"/> Unknown                                                                                                                                                          |                    |                                                                                                                                                                                                                                                                                                  |              |

February 19, 2004

Page 1 of 5

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**CENTERS FOR DISEASE CONTROL AND PREVENTION**  
 SAFER • HEALTHIER • PEOPLE™



Influenza A (H5) Domestic Case Screening Form 1.0  
(continued from previous page)

### Epidemiologic Risk Factors

CDC Case ID:

#### 5. Travel/Exposures

- A. In the 10 days prior to illness onset, did the patient travel to any of the countries listed in the table below? If yes\*, please fill in arrival and departure dates for all countries that apply.

☐ Yes\* ☐ No\*\* ☐ Unknown

\*\*If patient did not travel outside U.S., skip to question 6.

| Country                              | Arrival Date | Departure Date | Country                                   | Arrival Date | Departure Date |
|--------------------------------------|--------------|----------------|-------------------------------------------|--------------|----------------|
| <input type="checkbox"/> Afghanistan |              |                | <input type="checkbox"/> Myanmar (Burma)  |              |                |
| <input type="checkbox"/> Bangladesh  |              |                | <input type="checkbox"/> Nepal            |              |                |
| <input type="checkbox"/> Brunei      |              |                | <input type="checkbox"/> North Korea      |              |                |
| <input type="checkbox"/> Cambodia    |              |                | <input type="checkbox"/> Oman             |              |                |
| <input type="checkbox"/> China       |              |                | <input type="checkbox"/> Pakistan         |              |                |
| <input type="checkbox"/> Hong Kong   |              |                | <input type="checkbox"/> Papua New Guinea |              |                |
| <input type="checkbox"/> India       |              |                | <input type="checkbox"/> Philippines      |              |                |
| <input type="checkbox"/> Indonesia   |              |                | <input type="checkbox"/> Saudi Arabia     |              |                |
| <input type="checkbox"/> Iran        |              |                | <input type="checkbox"/> Singapore        |              |                |
| <input type="checkbox"/> Iraq        |              |                | <input type="checkbox"/> South Korea      |              |                |
| <input type="checkbox"/> Israel      |              |                | <input type="checkbox"/> Syria            |              |                |
| <input type="checkbox"/> Japan       |              |                | <input type="checkbox"/> Taiwan           |              |                |
| <input type="checkbox"/> Jordan      |              |                | <input type="checkbox"/> Thailand         |              |                |
| <input type="checkbox"/> Laos        |              |                | <input type="checkbox"/> Turkey           |              |                |
| <input type="checkbox"/> Lebanon     |              |                | <input type="checkbox"/> Viet Nam         |              |                |
| <input type="checkbox"/> Macao       |              |                | <input type="checkbox"/> Yemen            |              |                |
| <input type="checkbox"/> Malaysia    |              |                |                                           |              |                |

For the questions 5B to 5E,

In the 10 days prior to illness onset, **while in the countries** listed above . . .

- B. Did the patient come within 1 meter (3 feet) of any live poultry or domesticated birds (e.g. visited a poultry farm, a household raising poultry, or a bird market)?

☐ Yes\* ☐ No ☐ Unknown

If Yes\*

- C. Did patient touch any recently butchered poultry?

☐ Yes ☐ No ☐ Unknown

- D. Did the patient visit or stay in the same household with anyone with pneumonia or severe flu-like illness?

☐ Yes ☐ No ☐ Unknown

- E. Did the patient visit or stay in the same household with a suspected human influenza A(H5) case?\*

☐ Yes ☐ No ☐ Unknown

- F. Did the patient visit or stay in the same household with a known human influenza A(H5) case?\*

☐ Yes ☐ No ☐ Unknown

\* SEE Influenza A (H5): Interim U.S. Case Definitions

February 19, 2004

Page 2 of 5



Influenza A (H5) Domestic Case Screening Form 1.0  
(continued from previous page)

CDC ID:

#### 6. Exposure for Non Travelers

For patients whom did not travel outside the U.S.,  
**In the 10 days prior to illness onset**, did the patient visit or stay  
in the same household with a traveler returning from one of  
the countries listed above who developed pneumonia or severe  
flu-like illness?

☐ Yes\* ☐ No ☐ Unknown

If yes\*, was the contact a confirmed or suspected H5 case  
patient?

☐ Yes\* ☐ No ☐ Unknown

If yes\*: CDC ID: \_\_\_\_\_ STATE ID: \_\_\_\_\_

#### Laboratory Evaluation

#### 7. State and local level influenza test results

##### Specimen 1

☐ NP swab ☐ Bronchoalveolar lavage specimen (BAL)  
☐ NP aspirate ☐ OP swab ☐ Other \_\_\_\_\_

Date Collected:

\_\_\_ / \_\_\_ / \_\_\_  
m m d d y y y y

Test Type:

☐ RT-PCR ☐ Direct fluorescent antibody (DFA)  
☐ Viral Culture ☐ Rapid Antigen Test\*

Result:

☐ Influenza A ☐ Influenza B  
☐ Influenza (type unk)  
☐ Negative ☐ Pending

\*Name of Rapid Test:

##### Specimen 2

☐ NP swab ☐ Bronchoalveolar lavage specimen (BAL)  
☐ NP aspirate ☐ OP swab ☐ Other \_\_\_\_\_

Date Collected:

\_\_\_ / \_\_\_ / \_\_\_  
m m d d y y y y

Test Type:

☐ RT-PCR ☐ Direct fluorescent antibody (DFA)  
☐ Viral Culture ☐ Rapid Antigen Test\*

Result:

☐ Influenza A ☐ Influenza B  
☐ Influenza (type unk)  
☐ Negative ☐ Pending

\*Name of Rapid Test:

##### Specimen 3

☐ NP swab ☐ Bronchoalveolar lavage specimen (BAL)  
☐ NP aspirate ☐ OP swab ☐ Other \_\_\_\_\_

Date Collected:

\_\_\_ / \_\_\_ / \_\_\_  
m m d d y y y y

Test Type:

☐ RT-PCR ☐ Direct fluorescent antibody (DFA)  
☐ Viral Culture ☐ Rapid Antigen Test\*

Result:

☐ Influenza A ☐ Influenza B  
☐ Influenza (type unk)  
☐ Negative ☐ Pending

\*Name of Rapid Test:

February 19, 2004

Page 3 of 5

Influenza A (H5) Domestic Case Screening Form 1.0  
(continued from previous page)

CDC ID:

#### 8. List specimens sent to the CDC

Select a SOURCE\* from the following list for each specimen: Serum (acute), serum (convalescent), NP swab, NP aspirate, bronchoalveolar lavage specimen (BAL), OP swab, tracheal aspirate, or tissue

|                                            |             |                               |
|--------------------------------------------|-------------|-------------------------------|
| Specimen 1:                                | Source*:    | Collected :                   |
| <input type="checkbox"/> Clinical Material | -----       | ____ / ____ / ____            |
| <input type="checkbox"/> Extracted RNA     |             | m m d d y y y y               |
| <input type="checkbox"/> Virus Isolate     |             | Date Sent: ____ / ____ / ____ |
|                                            |             | m m d d y y y y               |
| Specimen 2:                                | Source*:    | Collected :                   |
| <input type="checkbox"/> Clinical Material | -----       | ____ / ____ / ____            |
| <input type="checkbox"/> Extracted RNA     |             | m m d d y y y y               |
| <input type="checkbox"/> Virus Isolate     |             | Date Sent: ____ / ____ / ____ |
|                                            |             | m m d d y y y y               |
| Specimen 3:                                | Source*:    | Collected :                   |
| <input type="checkbox"/> Clinical Material | -----       | ____ / ____ / ____            |
| <input type="checkbox"/> Extracted RNA     |             | m m d d y y y y               |
| <input type="checkbox"/> Virus Isolate     |             | Date Sent: ____ / ____ / ____ |
|                                            |             | m m d d y y y y               |
| Specimen 4:                                | Source*:    | Collected :                   |
| <input type="checkbox"/> Clinical Material | -----       | ____ / ____ / ____            |
| <input type="checkbox"/> Extracted RNA     |             | m m d d y y y y               |
| <input type="checkbox"/> Virus Isolate     |             | Date Sent: ____ / ____ / ____ |
|                                            |             | m m d d y y y y               |
| Specimen 5:                                | Source*:    | Collected :                   |
| <input type="checkbox"/> Clinical Material | -----       | ____ / ____ / ____            |
| <input type="checkbox"/> Extracted RNA     |             | m m d d y y y y               |
| <input type="checkbox"/> Virus Isolate     |             | Date Sent: ____ / ____ / ____ |
|                                            |             | m m d d y y y y               |
| Carrier:                                   | Tracking #: |                               |

#### 9. Case Notes:

February 19, 2004

Page 4 of 5







## supplement 2 laboratory diagnostics

### TABLE OF CONTENTS

|                                                                                                                                                                                                   |       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|
| SUMMARY OF ROLES AND RESPONSIBILITIES FOR PUBLIC HEALTH AND CLINICAL LABORATORIES IN LABORATORY DIAGNOSTICS.....                                                                                  | S2-2  |
| S2-I. RATIONALE .....                                                                                                                                                                             | S2-3  |
| S2-II. OVERVIEW .....                                                                                                                                                                             | S2-3  |
| S2-III. RECOMMENDATIONS FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS .....                                                                                                                    | S2-4  |
| A. Laboratory support for seasonal influenza surveillance .....                                                                                                                                   | S2-4  |
| B. Laboratory testing for novel influenza subtypes .....                                                                                                                                          | S2-4  |
| 1. Testing for human cases of avian influenza .....                                                                                                                                               | S2-4  |
| 2. Testing for human influenza strains with pandemic potential .....                                                                                                                              | S2-5  |
| C. Laboratory planning to support the response to an influenza pandemic .....                                                                                                                     | S2-5  |
| 1. Detection and characterization of novel influenza strains .....                                                                                                                                | S2-6  |
| 2. Laboratory reporting.....                                                                                                                                                                      | S2-6  |
| 3. Distribution of diagnostic reagents and test information .....                                                                                                                                 | S2-6  |
| 4. Laboratory surge capacity planning.....                                                                                                                                                        | S2-6  |
| a) Staffing and training.....                                                                                                                                                                     | S2-6  |
| b) Supplies and equipment.....                                                                                                                                                                    | S2-6  |
| c) Specimen management .....                                                                                                                                                                      | S2-7  |
| 5. Partnerships with healthcare providers and clinical laboratories.....                                                                                                                          | S2-7  |
| S2-IV. RECOMMENDATIONS FOR THE PANDEMIC PERIOD .....                                                                                                                                              | S2-7  |
| A. Laboratory support for disease surveillance .....                                                                                                                                              | S2-7  |
| B. Laboratory support for clinicians .....                                                                                                                                                        | S2-8  |
| C. Biocontainment procedures .....                                                                                                                                                                | S2-8  |
| D. Occupational health issues for laboratory workers.....                                                                                                                                         | S2-8  |
| Box 1. Use of diagnostic assays during an influenza pandemic .....                                                                                                                                | S2-9  |
| Box 2. Laboratory support for seasonal influenza surveillance.....                                                                                                                                | S2-10 |
| Box 3. Avian influenza strains with high and low pathogenicity.....                                                                                                                               | S2-11 |
| Appendix 1. Influenza diagnostic assays.....                                                                                                                                                      | S2-12 |
| Appendix 2. Interim recommendations: Enhanced U.S. surveillance and diagnostic evaluation to identify cases of human infection with avian influenza A (H5N1) .....                                | S2-17 |
| Appendix 3. Reference testing guidelines for potential pandemic strains of influenza .....                                                                                                        | S2-18 |
| Appendix 4. Laboratory biosafety guidelines for handling and processing specimens or isolates of novel influenza strains.....                                                                     | S2-19 |
| Appendix 5. Guidelines for collecting and shipping specimens for influenza diagnostics.....                                                                                                       | S2-20 |
| Appendix 6. Rapid diagnostic testing for influenza .....                                                                                                                                          | S2-24 |
| Appendix 7. Guidelines for medical surveillance of laboratory research personnel working with novel strains of influenza, including avian strains and other strains with pandemic potential ..... | S2-28 |

## **SUMMARY OF ROLES AND RESPONSIBILITIES FOR PUBLIC HEALTH AND CLINICAL LABORATORIES IN LABORATORY DIAGNOSTICS**

### **INTERPANDEMIC AND PANDEMIC ALERT PERIODS**

#### **Clinical and hospital laboratories:**

- Work with state and local health departments to address laboratory surge capacity issues and train personnel in management of respiratory specimens during an influenza pandemic.
- Send clearly labeled specimens from patients with suspected novel influenza to state or local health departments. Hospital labs should NOT attempt to isolate influenza viruses from patients with suspected novel influenza virus infection.
- Institute surveillance for influenza-like illnesses (ILI) among laboratory personnel working with novel influenza viruses.

#### **State and local public health laboratories:**

- Work with federal partners to enhance laboratory-based monitoring of seasonal influenza virus subtypes, as described in Supplement 1.
- Conduct testing for novel subtypes of influenza viruses only if BSL-3 biocontainment conditions with enhancements are available.
- Institute surveillance for ILI among laboratory personnel.
- Conduct preparedness planning to support the response to an influenza pandemic.

#### **HHS responsibilities:**

- Monitor preparedness and laboratory capacity for seasonal influenza and assess surge capacity.
- Provide technical support to the WHO Influenza Network and ministries of health and agriculture, as requested, in analyzing novel influenza virus subtypes—including avian isolates and human isolates with pandemic potential—in terms of antigenicity, RNA sequence, and drug sensitivities.
- Work with state and local public health laboratories to ensure that diagnostics for identifying “pandemic alert” strains are available and are used safely and effectively.
- Provide guidance on biosafety and safe handling of respiratory specimens from potential cases of pandemic influenza.

### **PANDEMIC PERIOD**

#### **Clinical and hospital laboratories:**

- Scale up to manage increased numbers of requests for influenza testing.
- Send selected specimens from possible pandemic influenza patients to state or local health departments.

#### **State and local public health laboratories:**

- Scale up to manage increased numbers of requests for influenza testing.
- Work with federal partners to provide healthcare providers and clinical laboratories with guidelines on all aspects of specimen management and diagnostic testing.

- Work with federal partners to monitor the pandemic virus and conduct special studies related to vaccine development, or other aspects of the response.

#### **HHS responsibilities:**

- Work with U.S. and global partners to characterize new pandemic viruses in terms of antigenicity, RNA sequence, and drug sensitivities, and to monitor changes over time.
- Work with state and local public health laboratories to ensure the availability and the safe and effective use of diagnostic tests and reagents.
- Conduct reference testing of positive samples, and perform viral isolation, especially at the beginning of a pandemic.
- Provide laboratory support for the selection of seed strains to be used in a vaccine against the pandemic virus.

## **S2-I. RATIONALE**

The goals of diagnostic testing during a pandemic are to:

- Identify the earliest U.S. cases of pandemic influenza (whether the pandemic begins in the United States or elsewhere).
- Support disease surveillance to monitor the pandemic's geographic spread and impact of interventions.
- Facilitate clinical treatment by distinguishing patients with influenza from those with other respiratory illnesses.
- Monitor circulating viruses for antiviral resistance.

Diagnostic testing for pandemic influenza virus may involve a range of laboratory assays, including rapid antigen tests, reverse-transcription polymerase chain reaction (RT-PCR), virus isolation, and immunofluorescence antibody (IFA) assays (see Box 1 and Appendix 1).

During the earliest stages of a pandemic, public health, hospital, and clinical laboratories might receive a large and potentially overwhelming volume of clinical specimens. Pre-pandemic planning is therefore essential to ensure the timeliness of diagnostic testing and the availability of diagnostic supplies and reagents, address staffing issues, and disseminate protocols for safe handling and shipping of specimens. Once a pandemic is underway, the need for laboratory confirmation of clinical diagnoses may decrease as the virus becomes widespread.

## **S2-II. OVERVIEW**

Supplement 2 provides recommendations to state and local public health partners and other laboratories on the use of diagnostic tests to detect, characterize, and monitor novel subtypes of influenza, including avian influenza A (H5N1) and other viruses with pandemic potential. The recommendations for the Interpandemic and Pandemic Alert Periods focus on laboratory testing in support of seasonal influenza surveillance, laboratory-based detection of novel influenza subtypes, and preparedness planning to support the laboratory component of the response to a pandemic (e.g., detection and characterization of viruses, case reporting, specimen management, surge capacity). The recommendations for the Pandemic Period focus on the provision of laboratory support for disease surveillance and to assist clinicians and hospitals. The recommendations also cover occupational health issues for laboratory workers.



## S2-III. RECOMMENDATIONS FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS

### A. Laboratory support for seasonal influenza surveillance

State and local public health laboratories and clinical laboratories (including hospital and private commercial laboratories) should continue to participate in laboratory-based surveillance for new subtypes of influenza through the U.S.-based laboratories in the World Health Organization (WHO) Global Influenza Surveillance Network and the National Respiratory and Enteric Virus Surveillance System (NREVSS). Additional information on seasonal influenza surveillance (including surveillance for influenza mortality and pediatric hospitalizations) is provided in **Supplement 1**. Information on the WHO Global Influenza Surveillance Network and NREVSS is provided in **Box 2**.

### B. Laboratory testing for novel influenza subtypes

During the Pandemic Alert Period, state and local health departments, hospitals, and clinicians should enhance surveillance to identify patients who may present with possible cases of novel influenza (see **Appendix 2**). Health Alert Network (HAN) messages will be issued, as needed, to provide updates and guidance as new situations arise.

State and local public health laboratories should be prepared to process and, in some instances, test—if they have the capability (see below)—specimens from suspected cases of infection with:

- Avian influenza A (H5N1) and other avian influenza viruses
- Other animal influenza viruses (e.g., swine influenza viruses)
- New or re-emergent human influenza viruses (e.g., H2) with pandemic potential

Clinicians should contact their state or local health departments if they suspect a human case of infection with any novel influenza A virus. State and local health departments, in turn, should contact CDC via the CDC Emergency Response Hotline: 770-488-7100.

Guidelines on when to send specimens or isolates of suspected novel avian or human strains to CDC for reference testing are provided in **Appendix 3**.

#### 1. Testing for human cases of avian influenza

Currently, avian influenza strains implicated in human disease (in addition to influenza A [H5N1]) include the highly pathogenic avian influenza (HPAI) strain H7N7 and the low pathogenic avian influenza (LPAI) strains H9N2, H7N2, and H7N3 (see **Box 3**). As of October 2005, no laboratory-confirmed cases of human infection with influenza A (H5N1) had been reported in the United States. However, CDC has confirmed two non-fatal cases of avian A (H7N2) influenza in Virginia and New York (**Box 3**). As new U.S. cases of human infection with avian influenza viruses are reported, they will be posted at: [www.aphis.usda.gov/vs/birdbiosecurity/hpai.html](http://www.aphis.usda.gov/vs/birdbiosecurity/hpai.html) and at: [www.cdc.gov/flu](http://www.cdc.gov/flu).

Recommendations on laboratory testing for human cases of avian influenza are as follows:

- State public health laboratories may conduct testing to identify suspected subtypes of avian influenza, including H5 and H7, if appropriate laboratory capacity and biocontainment equipment are available. Because of the danger that HPAI strains present to the U.S. agricultural industry, U.S. Department of Agriculture (USDA) regulations require that HPAI strains such as H5N1 (which are classified as select agents) must be cultured using BSL-3 biocontainment conditions with enhancements (see **Appendix 4**).

- Public health laboratories that lack BSL-3 facilities may use RT-PCR with BSL-2 containment to test clinical specimens from suspected human cases of avian influenza to identify and subtype influenza A viruses (e.g., H1, H3, H5, and H7; see S2-III.C). Or, they may send specimens to CDC, using the collection, handling, and shipping procedures described in Appendix 5.

During the Pandemic Alert Period, specimens from suspected cases of human infection with novel influenza viruses should be sent for testing to public health laboratories with proper biocontainment facilities:

- RT-PCR – BSL-2
- Virus isolation – BSL-3 with enhancements

The American Society for Microbiology maintains a list of emergency contacts in state public health laboratories, which is available at: [www.asm.org/ASM/files/0000000527/labemergencycontacts\[1\].pdf](http://www.asm.org/ASM/files/0000000527/labemergencycontacts[1].pdf).

If an avian influenza strain—or a human virus variant that evolves from it—causes an influenza pandemic, it might become necessary to re-evaluate biocontainment requirements and select agent registration requirements for laboratory testing. CDC and the Laboratory Response Network (LRN) will assist USDA, as requested, in making such a decision.

## 2. Testing for human influenza strains with pandemic potential

During the Pandemic Alert Period, diagnostic laboratories should be on the alert for new human subtypes of influenza that might have pandemic potential. Recommendations are as follows:

- State and local public health laboratories that can detect human and avian influenza subtypes by RT-PCR should report all unusual subtypes to CDC via the Emergency Response Hotline (770-488-7100).
- Public health laboratories that can detect human (but not avian) influenza subtypes by IFA staining or RT-PCR should send influenza A isolates that cannot be subtyped to CDC. (If an avian strain is suspected, virus isolation and IFA should be performed under BSL-3 conditions with enhancements.)
- Public health laboratories should send specimens to CDC if a patient meets the clinical and epidemiologic criteria for infection with a novel influenza virus and:
  - Tests positive for influenza A by RT-PCR or by rapid diagnostic testing, *or*
  - Tests negative for influenza A by rapid diagnostic testing and/or RT-PCR testing for influenza is not available
- Clinical laboratories that receive diagnostic specimens from patients with suspected novel influenza (based on clinical and epidemiologic data) should contact their state or local health departments.
- If new or re-emergent human influenza strains with pandemic potential are suspected, laboratories should conduct RT-PCR only under BSL-2 containment conditions and viral culture only under BSL-3 conditions with enhancements (see Appendix 4).

## C. Laboratory planning to support the response to an influenza pandemic

Advance planning is essential to anticipate adequate laboratory capacity to support medical and public health partners during an influenza pandemic. Some aspects of this planning, such as surge capacity planning, can be coordinated with bioterrorism preparedness planning.

## 1. Detection and characterization of novel influenza strains

- As of October 2005, about 48 state and large local public health laboratories have received training in RT-PCR protocols for molecular detection of H1, H3, H5, and H7 subtypes. These laboratories should incorporate RT-PCR testing into their standard influenza laboratory activities. Real-time RT-PCR protocols are available through the website of the Association of Public Health Laboratories (APHL) and will be updated as required to monitor the appearance and evolution of novel influenza viruses. A positive RT-PCR test result for a novel influenza strain should be considered presumptive, pending testing by a second reference laboratory.
- State and local public health laboratories should provide hospitals and healthcare providers with information on how to contact the laboratory when a novel influenza subtype is suspected and how to handle, label, and ship clinical specimens for diagnostic evaluation.
- State and local public health laboratories should contact laboratories in their jurisdictions that conduct RT-PCR influenza testing or that have BSL-3 containment facilities to remind them to notify the state health department if they receive specimens from suspected cases of novel influenza.

## 2. Laboratory reporting

State and local health departments that report laboratory-confirmed seasonal influenza cases to CDC use a variety of reporting mechanisms, including faxes, the Public Health Information System (PHLIS), and a web-based NREVSS data-entry system. Cases of novel influenza should be reported to CDC by the same mechanisms.

## 3. Distribution of diagnostics reagents and test information

CDC is working with USDA and the Food and Drug Administration (FDA) to address any regulatory barriers to emergency distribution and use of diagnostic tests and reagents during a pandemic. CDC will provide updated preparedness information regarding diagnostic tests and reagents to state and local public health partners via the LRN and HAN.

## 4. Laboratory surge capacity planning

Health departments should assess projected statewide needs for scaled-up diagnostic activity during the early stages of a pandemic, in terms of laboratory staffing, training, reporting, and supplies, and should develop strategies to address them.

### a) Staffing and training

Laboratories should plan for increased staffing needs. Some strategies include:

- Cross-training personnel during the regular influenza season in the use of rapid diagnostic tests and RT-PCR protocols and in reporting results through existing surveillance systems
- Arranging to recruit and train temporary staff for employment during a pandemic

### b) Supplies and equipment

Laboratories are likely to require additional diagnostic supplies and equipment to process large numbers of samples during the initial stages of a pandemic. Some preparedness strategies include:

- Establishing the current level of diagnostic supplies, including personal protective equipment for laboratorians (e.g., gloves, masks)
- Assessing anticipated equipment and supply needs, and determining a trigger point for ordering extra resources. Laboratories should also consider the need for back-up sources of supplies if most laboratories in a state or large city rely on the same manufacturer for particular supplies or equipment.
- Determining how consumption of supplies will be tracked during a pandemic

### c) Specimen management

State and local health departments should inform and educate public health staff (including laboratorians), local physicians, and hospital workers on safe and effective methods for specimen collection and management, making use of the guidelines in Appendix 5, Guidelines for Collecting and Shipping Specimens for Influenza Diagnostics. Safety issues related to specimen handling are also addressed in Supplement 4.

Procedures for specimen collection, handling, and shipping during a pandemic will be the same as those used for seasonal disease surveillance. However, laboratory staff should anticipate shipping a much larger number of specimens in a very short time, especially during the early stages of a pandemic. Once the pandemic is underway and healthcare providers rely on clinical criteria and rapid test kits, more diagnostic activities may be conducted locally and fewer shipments may be needed.

## 5. Partnerships with healthcare providers and clinical laboratories

Good working relationships between healthcare providers and public health laboratories will facilitate diagnostic activities during a pandemic.

- Public health laboratories should continue to build partnerships with healthcare providers in their jurisdictions, including physicians who participate in the Sentinel Provider Network (SPN) during the regular influenza season (see Supplement 1).
- Public health laboratories should build partnerships with clinical laboratories and provide them with updated information and (if feasible) training in influenza diagnostics.

## S2-IV. RECOMMENDATIONS FOR THE PANDEMIC PERIOD

### A. Laboratory support for disease surveillance

- Public health, hospital, and clinical laboratories will support surveillance for pandemic influenza through the same mechanisms that support laboratory-based surveillance for seasonal influenza. CDC and the LRN will work with state and local health departments to make diagnostic testing for the pandemic virus readily available, both at CDC and at state and local public health laboratories that have implemented RT-PCR protocols.
- As soon as a pandemic strain has been identified, CDC's Influenza Laboratory will develop, produce, and disseminate RT-PCR and IFA reagents, as needed. As necessary, CDC and APHL will also update the RT-PCR protocol currently available to public health laboratories through the APHL website.
- As the pandemic continues, CDC will advise states on when confirmatory testing (i.e., subtyping) is required. Although confirmatory testing will be required when the pandemic begins, the level of testing will decrease as the virus becomes widespread.
- CDC will advise states on the percentage of isolates per week or month that they should send to CDC as part of efforts to monitor changes in the antigenicity and antiviral susceptibility of the pandemic virus. Throughout the pandemic, CDC will provide updated instructions on the collection of clinical and epidemiologic data that should accompany isolates. CDC could ask some state public health laboratories to perform virus isolation or RT-PCR subtyping before sending specimens to CDC.
- CDC may work with the U.S.-based WHO collaborating laboratories, NREVSS laboratories, and/or Emerging Infectious Program sites ([www.cdc.gov/ncidod/osr/site/eip/index.htm](http://www.cdc.gov/ncidod/osr/site/eip/index.htm)) to conduct special studies or establish additional laboratory-based surveillance systems to answer critical questions related to vaccine development or other aspects of the public health response. For example, CDC and state and local partners could conduct serosurveys to determine the number of persons who develop antibodies to the pandemic virus over time.

## B. Laboratory support for clinicians

- When a pandemic begins, public health and clinical laboratories will scale up to manage increased numbers of requests for influenza testing. As part of this effort, CDC will work with state and local public health laboratories and the LRN to provide clinical laboratories with guidelines for safe handling, processing, and rapid diagnostic testing of clinical specimens from patients who meet the case definition for pandemic influenza.

If private laboratories perform RT-PCR testing during the early phase of an influenza pandemic, the results should be confirmed in consultation with the state public health laboratory.

- State and local health laboratories should provide local healthcare providers with:
  - Specimen submission forms that specify the clinical and epidemiologic data that should accompany clinical specimens sent to state public health laboratories. (During the early stages of a pandemic, clinicians should include information on patients' symptoms and risk factors, if known.)
  - Rapid communication of test results and reminders that a negative test result (especially by rapid diagnostic testing) might not rule out influenza and should not affect patient management or infection control decisions.
  - Guidance on the use of commercially available rapid diagnostic tests for the detection of influenza A. These tests may be used by physicians to supplement clinical diagnoses of pandemic influenza. Because the sensitivity of rapid diagnostic kits might not be optimal, physicians should take their positive and negative predictive values into consideration when interpreting test results (Appendix 6).
  - Guidance on which specimens to send to state public health laboratories as the pandemic continues.

## C. Biocontainment procedures

During an influenza pandemic, laboratory procedures should be conducted under appropriate biosafety conditions:

- Commercial antigen detection testing for influenza should be conducted using BSL-2 work practices.
- Public health laboratories may conduct RT-PCR testing using BSL-2 work practices and virus isolation using BSL-3 practices with enhancements.

Additional information on laboratory biocontainment is provided in Appendix 4.

## D. Occupational health issues for laboratory workers

To protect the health of laboratory workers during a pandemic, public health, clinical, and hospital laboratories should maintain the safety practices used during the Interpandemic and Pandemic Alert Periods. These include:

- Conducting laboratory procedures under appropriate biocontainment conditions
- Encouraging routine vaccination of all eligible laboratory personnel who are exposed to specimens from patients with respiratory infections

Guidelines for medical surveillance of laboratory personnel are provided in Appendix 7.

## BOX 1. USE OF DIAGNOSTIC ASSAYS DURING AN INFLUENZA PANDEMIC

Public health and clinical laboratories will use different types of diagnostic tests for influenza at different stages of a pandemic. Each of the tests discussed below is described in detail in Appendix 1.

### Virus Isolation

Virus isolation—growing the viral strain in cell culture—is the “gold standard” for influenza diagnostics because it confirms that the virus is infectious. During a pandemic, virus isolation followed by antigenic and genetic (sequencing) analysis will be used to characterize the earliest pandemic isolates, as well as to monitor their evolution during the pandemic. Laboratories that participate in the WHO Global Influenza Surveillance Network typically use virus isolation followed by hemagglutination inhibition (HAI), IFA staining, or RT-PCR to monitor circulating seasonal strains of influenza. If clinical and epidemiologic data suggest that a human case of influenza might be due to infection with avian influenza A (H5N1) or another highly pathogenic avian influenza strain (see Box 3), the virus should not be cultured except under BSL-3 conditions with enhancements. Laboratories that lack BSL-3 enhanced facilities may either perform RT-PCR subtyping using BSL-2 containment procedures or send the specimen to CDC for isolation and characterization.

### Immunofluorescence Antibody Staining

IFA staining following virus isolation can be used to identify influenza types (A, B) and influenza A HA subtypes using a panel of specific antisera. In some cases, IFA can be used for direct testing of cells pelleted from original clinical samples. CDC’s Influenza Branch produces and distributes a reagent kit to WHO collaborating laboratories that includes monoclonal antibodies for typing and subtyping currently circulating influenza viruses by IFA. Many laboratories use commercially available reagents to type influenza viruses by direct immunofluorescence tests (DFA).

### RT-PCR Subtyping

Influenza specimens may also be typed and subtyped using RT-PCR, which does not require *in vitro* growth or isolation of virus. As of October 2005, CDC has trained scientists from 48 states to use RT-PCR subtyping to identify human and avian HA subtypes of public health concern. APHL members can access protocols and sequences of primers and probes that can be used for typing and subtyping on the APHL website.

### Serologic Tests

Tests based on detection of antibodies in patient sera—e.g., enzyme-linked immunosorbent assay (ELISA), HAI, and microneutralization assay—can be used to retrospectively confirm influenza infection. Although microneutralization assay is the most comprehensive test for detection in humans of antibodies to avian influenza viruses, it is available in only a few state public health laboratories.

### Rapid Diagnostic Tests

Several rapid diagnostic test kits based on antigen detection are commercially available for influenza. Laboratories in outpatient settings and hospitals can use these tests to detect influenza viruses within 30 minutes. Some tests can detect influenza A viruses (including avian strains); others can detect influenza A and B viruses without distinguishing between them, and some can distinguish between influenza A and B viruses. The type of specimens used in these tests (i.e., nasal wash/aspirate, nasopharyngeal swabs, or nasal swab or throat swab) may also vary. Like RT-PCR, rapid diagnostic tests do not require *in vitro* growth or isolation of virus. During a pandemic, rapid diagnostic tests will be widely used to distinguish influenza A from other respiratory illnesses. See Appendix 6 for additional information.

## **BOX 2. LABORATORY SUPPORT FOR SEASONAL INFLUENZA SURVEILLANCE**

### **U.S. Collaborating Laboratories of the WHO Global Influenza Surveillance Network**

All state and several large local public health laboratories, as well as about 25 tertiary-care hospital and academic center laboratories, participate as U.S. collaborating laboratories in the WHO Global Influenza Surveillance Network, which collects worldwide data on circulating strains of influenza viruses. These data are used to develop recommendations for the formulation of each year's influenza vaccines, as well as to detect new human influenza viruses that might have pandemic potential. CDC's Influenza Laboratory serves as the WHO Collaborating Center for Surveillance, Epidemiology, and Control of Influenza, along with the WHO Collaborating Centers for Reference and Research on Influenza in Australia, Japan, and the United Kingdom.

The U.S.-based WHO collaborating laboratories provide CDC with weekly reports of laboratory-confirmed cases of influenza A and B viruses, by age group. These laboratories typically use virus isolation followed by antigenic testing with IFA staining or HAI—or by molecular testing with RT-PCR—to identify known subtypes of human influenza viruses. If unusual subtypes are detected, or if the specimens cannot be subtyped using available techniques, the specimens are sent to CDC for further testing.

### **NREVSS Collaborating Laboratories**

The National Respiratory and Enteric Virus Surveillance System (NREVSS; <http://www.cdc.gov/ncidod/dvrd/revb/nrevss/>) includes more than 90 laboratories throughout the country, including many hospital laboratories, some state public health laboratories, and a few private commercial laboratories. About 40 of the NREVSS laboratories are also WHO collaborating laboratories.

Like the WHO collaborating laboratories, NREVSS laboratories provide CDC with weekly reports of laboratory-confirmed cases of influenza A and B viruses. These laboratories typically test respiratory specimens with commercially available rapid diagnostic tests. Several NREVSS laboratories also perform virus isolation followed by rapid diagnostic tests or antigenic typing by IFA. If untypable viruses or unusual subtypes are detected, the specimens are sent to the state public health laboratory or to CDC for further testing.



### BOX 3. AVIAN INFLUENZA STRAINS WITH HIGH AND LOW PATHOGENICITY

The U.S. Department of Agriculture (USDA) classifies avian influenza viruses as low pathogenic avian influenza (LPAI) viruses or highly pathogenic avian influenza (HPAI) viruses, based on characteristics of a virus' hemagglutinin cleavage site or its virulence in birds, as determined by laboratory testing. LPAI strains are endemic in wild birds worldwide and are responsible for most avian influenza outbreaks in poultry. LPAI strains with H5 and H7 subtypes sometimes evolve into highly pathogenic forms. HPAI strains are extremely contagious and cause severe illness and high mortality rates in poultry.

LPAI strains include:

- H5N2, the cause of poultry outbreaks in New York, Maine, and California in 2002
- H7N2, the cause of poultry outbreaks in Delaware, Maryland, and New Jersey in 2004

HPAI strains include:

- H5N1, the cause of major poultry outbreaks in Southeast Asia
- H7N7, the cause of a 2003 outbreak in the Netherlands
- H7N3, the cause of a 2004 outbreak in British Columbia
- H5N2, the cause of a 2004 outbreak in poultry in Texas

The 2004 outbreak in Texas was the first HPAI outbreak in the United States since a previous outbreak of H5N2 in 1983–84 in the northeastern United States. The 1983–84 disease control effort involved the destruction of approximately 17 million birds and cost more than \$70 million.

Although avian influenza A viruses do not usually infect humans, several instances of human infections of avian influenza have been reported since 1997. Cases of avian influenza infection in humans are apparently caused by contact with infected poultry or with surfaces contaminated with avian influenza viruses.

LPAI strains associated with human infection include:

- H9N2, which caused three cases of influenza-like illness in Hong Kong between 1999 and 2003, and other cases in China in 1998 and 1999
- H7N2, which was detected by serology in one person involved in the culling of sick chickens during the response to a poultry outbreak in Virginia in 2002, and was isolated from a New York resident in 2003 (unknown source of the infection)

HPAI viruses associated with human infection include:

- H5N1, which caused 51 deaths in Southeast Asia between January 2004 and April 2005
- H7N7, which caused the death of a veterinarian as well as 83 cases of mild human disease (including conjunctivitis) during the 2003 poultry outbreak in the Netherlands.
- H7N3, which caused 2 cases of very mild human disease (conjunctivitis, headache) in persons culling sick poultry in British Columbia in 2004

## APPENDIX 1. INFLUENZA DIAGNOSTIC ASSAYS

Among the several types of assays used to detect influenza, rapid antigen tests, reverse-transcription polymerase chain reaction (RT-PCR), viral isolation, immunofluorescence assays (IFA), and serology are the most commonly used. The sensitivity and specificity of any test for influenza will vary by the laboratory that performs the test, the type of test used, and the type of specimen tested. A chart that lists influenza diagnostic procedures and commercially available rapid diagnostic tests follows more detailed descriptions provided below.

### Virus Isolation

**Biocontainment level: Interpandemic and Pandemic Alert Periods – BSL-3 with enhancements; Pandemic Period – BSL-2**

Virus isolation is a highly sensitive and very useful technique when the clinical specimens are of good quality and have been collected in a timely manner (optimally within 3 days of the start of illness). Isolation of a virus in cell culture along with the subsequent identification of the virus by immunologic or genetic techniques are standard methods for virus diagnosis. Virus isolation amplifies the amount of virus from the original specimen, making a sufficient quantity of virus available for further antigenic and genetic characterization and for drug-susceptibility testing if required. Virus isolation is considered the “gold standard” for diagnosis of influenza virus infections.

Highly pathogenic avian influenza (HPAI) viruses are BSL-3 agents. During the Interpandemic and Pandemic Alert Periods, laboratories should attempt to culture HPAI viruses—as well as other influenza viruses with pandemic potential—only under BSL-3 conditions with enhancements in order to optimally reduce the risk of a novel influenza virus subtype spreading to persons or animals. During the Pandemic Period, biocontainment of BSL-2 is appropriate to prevent laboratory-acquired infection and the virus will already be widespread.

In recent years, the use of cell lines has surpassed the use of embryonated eggs for culturing of influenza viruses, although only viruses grown in embryonated eggs are used as seed viruses for vaccine production. Because standard isolation procedures require several days to yield results, they should be used in combination with the spin-amplification shell-vial method. The results of these assays can be obtained in 24–72 hours, compared to an average of 4.5 days using standard culture techniques. Spin-amplification should not be performed using 24-well plates because of increased risk of cross-contamination. The most effective combination of cell lines recommended for public health laboratories is primary rhesus monkey for standard culture, along with Madin Darby Canine Kidney (MDCK) in shell vial.<sup>1</sup> The use of these two cell lines in combination has demonstrated maximum sensitivity over time for recovery of evolving influenza strains. Some clinical laboratories have recently reported good isolation rates using commercially available cell-line mixed-cell combinations; however, data are lacking on the performance of these mixed cells with new subtypes of Influenza A viruses.

Appropriate clinical specimens for virus isolation include nasal washes, nasopharyngeal aspirates, nasopharyngeal and throat swabs, tracheal aspirates, and bronchoalveolar lavage. Ideally, specimens should be collected within 72 hours of the onset of illness.

Viral culture isolates are used to provide specific information regarding circulating influenza subtypes and strains. This information is needed to compare current circulating influenza strains with vaccine strains, to guide decisions on influenza treatment and chemoprophylaxis, and to select vaccine strains for the coming year. Virus isolates also are needed to monitor

<sup>1</sup> The shell-vial technique is described in: *Manual of Clinical Virology*, 3rd edition. Steven Specter, Richard Hodinka, and Stephen Young, eds. ASM Press, 2000.

the emergence of antiviral resistance and of novel influenza A subtypes that might pose a pandemic threat. During outbreaks of influenza-like illness, viral culture may help identify other causes of illness when influenza is not the etiology (except when using MDCK cells or the MDCK shell-vial technique).

## Immunofluorescence Assays

**Biocontainment level:** *BSL-2 when performed directly on clinical specimens; if used on cultures for earlier detection of virus, biocontainment recommendations for viral culture apply*

Direct (DFA) or indirect (IFA) immunofluorescence antibody staining of virus-infected cells is a rapid and sensitive method for diagnosis of influenza and other viral infections. DFA and IFA can also be used to type and subtype influenza viruses using commercially available monoclonal antibodies specific for the influenza virus HA. The sensitivity of these methods is greatly influenced by the quality of the isolate, the specificity of the reagents used, and the experience of the person(s) performing, reading, and interpreting the test.

Although IFA can be used to stain smears of clinical specimens directly, when rapid diagnosis is needed it is preferable to first increase the amount of virus through growth in cell culture. For HPAI isolates, attempts to culture the virus should be made only under BSL-3 conditions with enhancements.

## Reverse-Transcription Polymerase Chain Reaction (RT-PCR)

**Biocontainment level:** *BSL-2*

PCR can be used for rapid detection and subtyping of influenza viruses in respiratory specimens. Because the influenza genome consists of single-stranded RNA, a complementary DNA (cDNA) copy of the viral RNA must be synthesized using the reverse-transcriptase (RT) enzyme prior to the PCR reaction.

Laboratories can obtain CDC protocols and sequences of primers and probes for rapid RT-PCR detection of human and avian HA subtypes of current concern at the APhL website (available for members only). These protocols use real-time RT-PCR methods with fluorescent-labeled primers that allow automatic, semi-quantitative estimation of the input template. The RT-PCR results are analyzed and archived electronically, without the need for gel electrophoresis and photographic recording. A large number of samples may be analyzed at the same time, reducing the risk of carry-over contamination.

As with all PCR assays, interpretation of real-time RT-PCR tests must account for the possibility of false-negative and false-positive results. False-negative results can arise from poor sample collection or degradation of the viral RNA during shipping or storage. Application of appropriate assay controls that identify poor-quality samples (e.g., an extraction control and, if possible, an inhibition control) can help avoid most false-negative results.<sup>2</sup>

The most common cause of false-positive results is contamination with previously amplified DNA. The use of real-time RT-PCR helps mitigate this problem by operating as a contained system. A more difficult problem is the cross-contamination that can occur between specimens during collection, shipping, and aliquoting in the laboratory. Use of multiple negative control samples in each assay and a well-designed plan for confirmatory testing can help ensure that laboratory contamination is detected and that negative specimens are not inappropriately identified as influenza-positive.

Specimens that test positive for a novel subtype of influenza virus should be forwarded to CDC for confirmatory testing. (Due to the possibility of contamination, it is important to provide original clinical material.) All laboratory results should be interpreted in the context of the clinical and epidemiologic information available on the patient.

<sup>2</sup> CDC is working with the private sector to provide inactivated RNA virus for use as RT-PCR controls for influenza A (H5) testing in LRN laboratories. CDC is working with USDA to resolve any permit issues that might affect the ability of LRN members to use these controls.

## Rapid Diagnostic Tests

### *Biocontainment level: BSL-2*

Commercial rapid diagnostic tests can be used in outpatient settings to detect influenza viruses within 30 minutes. These rapid tests differ in the types of influenza viruses they can detect and in their ability to distinguish among influenza types. Different tests can 1) detect influenza A viruses only (including avian strains); 2) detect both influenza A and B viruses, without distinguishing between them; or 3) detect both influenza A and B viruses and distinguish between them.

The types of specimens acceptable for use (i.e., nasal wash/aspirate, nasopharyngeal swab, or nasal swab and throat swab) also vary by test. The specificity and, in particular, the sensitivity of rapid tests are lower than for viral culture and vary by test and specimen tested. The majority of rapid tests are >70% sensitive and >90% specific. Thus, as many as 30% of samples that would be positive for influenza by viral culture may give a negative rapid test result with these assays.

When interpreting results of a rapid influenza test, physicians should consider the level of influenza activity in the community. When influenza prevalence is low, positive rapid test results should be independently confirmed by culture or RT-PCR. When influenza is known to be circulating, clinicians should consider confirming negative tests with viral culture or other means because of the lower sensitivity of the rapid tests. Package inserts and the laboratory performing the test should be consulted for more details regarding use of rapid diagnostic tests. Additional information on diagnostic testing is provided at: <http://www.cdc.gov/flu/professionals/labdiagnosis.htm>. Detailed information on the use of rapid diagnostics tests is provided in Appendix 6.

## Serologic Tests<sup>3</sup>

### Hemagglutination Inhibition (HAI)

#### *Biocontainment level: BSL-2*

Serologic testing can be used to identify recent infections with influenza viruses. It can be used when the direct identification of influenza viruses is not feasible or possible (e.g., because clinical specimens for virus isolation cannot be obtained, cases are identified after shedding of virus has stopped, or the laboratory does not have the resources or staff to perform virus isolation).

Since most human sera contain antibodies to influenza viruses, serologic diagnosis requires demonstration of a four-fold or greater rise in antibody titer using paired acute and convalescent serum samples. HAI is the preferred diagnostic test for determining antibody rises. In general, acute-phase sera should be collected within one week of illness onset, and convalescent sera should be collected 2–3 weeks later.

There are two exceptions in which the collection of single serum samples can be helpful in the diagnosis of influenza. In investigations of outbreaks due to novel viruses, testing of single serum samples has been used to identify antibody to the novel virus. In other outbreak investigations, antibody test results from single specimens collected from persons in the convalescent phase of illness have been compared with results either from age-matched persons in the acute phase of illness or from non-ill controls. In such situations, the geometric mean titers between the two groups to a single influenza virus type or subtype can be compared. In general, these approaches are not optimal, and paired sera should be collected whenever possible.

Because HAI titers of antibodies in humans infected with avian influenza viruses are usually very low or even undetectable, more sensitive serologic tests, such as microneutralization, may be needed.

<sup>3</sup> Enzyme-linked immunoassay (EIA) is not included on this list because of non-specificity issues. Complement fixation is not included because it is currently out of use.

## Microneutralization Assay

**Biocontainment level: Interpandemic and Pandemic Alert Periods – BSL-3 with enhancements; Pandemic Period – BSL-2**

The virus neutralization test is a highly sensitive and specific assay for detecting virus-specific antibody in animals and humans. The neutralization test is performed in two steps: 1) a virus-antibody reaction step, in which the virus is mixed with antibody reagents, and 2) an inoculation step, in which the mixture is inoculated into a host system (e.g. cell cultures, embryonated eggs, or animals). The absence of infectivity constitutes a positive neutralization reaction and indicates the presence of virus-specific antibodies in human or animal sera.

The virus neutralization test gives the most precise answer to the question of whether or not a person has antibodies that can neutralize the infectivity of a given virus strain. The neutralization test has several additional advantages for detecting antibody to influenza virus. First, the assay primarily detects antibodies to the influenza virus HA and thus can identify functional, strain-specific antibodies in animal and human serum. Second, since infectious virus is used, the assay can be developed quickly upon recognition of a novel virus and before suitable purified viral proteins become available for use in other assays.

The microneutralization test is a sensitive and specific assay for detecting virus-specific antibody to avian influenza A (H5N1) in human serum and potentially for detecting antibody to other avian subtypes. Microneutralization can detect H5-specific antibody in human serum at titers that cannot be detected by HAI. Because antibody to avian influenza subtypes is presumably low or absent in most human populations, single serum samples can be used to screen for the prevalence of antibody to avian viruses. However, if infection of humans with avian viruses is suspected, the testing of paired acute and convalescent sera in the microneutralization test would provide a more definitive answer regarding the occurrence of infection. Conventional neutralization tests for influenza viruses based on the inhibition of cytopathogenic effect (CPE)-formation in MDCK cell cultures are laborious and rather slow, but in combination with rapid culture assay principles the neutralization test can yield results within 2 days. For HPAI viruses, neutralization tests should be performed at BSL-3 enhanced conditions.

## QUICK REFERENCE CHART OF INFLUENZA DIAGNOSTIC TESTS<sup>1</sup>

(From: *Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*. MMWR 2004;53(RR-6):1–40.

| Procedure                                                              | Influenza Types Detected  | Acceptable Specimens                                                                               | Time for Results         | Rapid result available |
|------------------------------------------------------------------------|---------------------------|----------------------------------------------------------------------------------------------------|--------------------------|------------------------|
| <b>Viral culture</b>                                                   | A and B                   | nasal wash/aspirate, NP swab,2 nasal aspirate, nasal swab and throat swab, sputum                  | 5–10 days <sup>3</sup>   | No                     |
| <b>Immunofluorescence Antibody Staining</b>                            | A and B                   | nasal wash/aspirate, NP swab,2 nasal aspirate, nasal swab and throat swab, sputum                  | 2–4 hours                | No                     |
| <b>RT-PCR<sup>5</sup></b>                                              | A and B                   | nasal wash/aspirate, NP swab,2 nasal aspirate, throat swab, bronchial wash, nasal aspirate, sputum | Hours                    | No                     |
| <b>Serology</b>                                                        | A and B                   | paired acute/convalescent serum samples <sup>6</sup>                                               | >2 weeks                 | No                     |
| <b>Rapid Diagnostic Tests</b>                                          |                           |                                                                                                    |                          |                        |
| Directigen Flu A <sup>7</sup> (Becton–Dickinson)                       | A                         | NP swab,2 throat swab, nasal wash, nasal aspirate                                                  | See insert               | Yes                    |
| Directigen Flu A+B <sup>7,9</sup> (Becton–Dickinson)                   | A and B                   | NP swab,2 throat swab, nasal wash, nasal aspirate                                                  | See insert               | Yes                    |
| FLU OIA <sup>7</sup> (Thermo Electron)                                 | A and B <sup>4</sup>      | NP swab,2 throat swab, nasal aspirate, sputum                                                      | See insert               | Yes                    |
| FLU OIA A/B <sup>7,9</sup> (Thermo Electron)                           | A and B                   | NP swab,2 throat swab, nasal aspirate, sputum                                                      | See insert               | Yes                    |
| XPECT Flu A/B <sup>7,9</sup> (Remel)                                   | A and B                   | Nasal wash, NP swab,2 throat swab                                                                  | See insert               | Yes                    |
| NOW Flu A Test <sup>7,9</sup><br>NOW Flu B Test <sup>7,9</sup> (Binax) | A<br>B                    | Nasal wash, NP swab2<br>Nasal wash, NP swab2                                                       | See insert<br>See insert | Yes<br>Yes             |
| QuickVue Influenza Test <sup>8</sup> (Quidel)                          | A and B <sup>4</sup>      | NP swab,2 nasal wash, nasal aspirate                                                               | See insert               | Yes                    |
| QuickVue Influenza A+B Test <sup>8</sup> (Quidel)                      | A and B <sup>9</sup><br>A | NP swab,2 nasal wash, nasal aspirate                                                               | See insert               | Yes                    |
| SAS Influenza A <sup>7,9</sup><br>SAS Influenza B <sup>7,9</sup>       | B<br>B                    | NP wash,2 NP aspirate2<br>NP wash,2 NP aspirate2                                                   | See insert<br>See insert | Yes<br>Yes             |
| ZstatFlu <sup>8</sup> (ZymeTx)                                         | A and B <sup>4</sup>      | throat swab                                                                                        | See insert               | Yes                    |

<sup>1</sup> The list might not include all FDA-approved test kits.

<sup>2</sup> NP = nasopharyngeal

<sup>3</sup> Shell-vial culture, if available, may reduce time for results to 2 days.

<sup>4</sup> Does not distinguish between influenza A and B virus infections.

<sup>5</sup> RT-PCR = reverse-transcription polymerase chain reaction

<sup>6</sup> A fourfold or greater rise in antibody titer from the acute- (collected within the first week of illness) to the convalescent-phase sample (collected 2–4 weeks after the acute sample) indicates recent infection.

<sup>7</sup> Moderately complex test that requires specific laboratory certification

<sup>8</sup> CLIA-waived test. Can be used in any office setting. Requires a certificate of waiver or higher laboratory certification

<sup>9</sup> Distinguishes between influenza A and B virus infections.

**Disclaimer:** Use of trade names or commercial sources is for identification only and does not imply endorsement by the Centers for Disease Control and Prevention or the Department of Health and Human Services.

## APPENDIX 2. INTERIM RECOMMENDATIONS: ENHANCED U.S. SURVEILLANCE AND DIAGNOSTIC EVALUATION TO IDENTIFY CASES OF HUMAN INFECTION WITH AVIAN INFLUENZA A (H5N1)

NOTE: This guidance pertains to the avian influenza A (H5N1) situation in October 2005. CDC will provide updated guidance for avian influenza A (H5N1) and for new situations, as needed, through the Health Alert Network (HAN).

Enhanced surveillance efforts by state and local health departments, hospitals, and clinicians are needed to identify patients at increased risk for influenza A (H5N1). Interim recommendations include the following:

Testing for avian influenza A (H5N1) is indicated for **hospitalized** patients with:

- Radiographically confirmed pneumonia, acute respiratory distress syndrome (ARDS), or other severe respiratory illness for which an alternative diagnosis has not been established, *and*
- History of travel within 10 days of symptom onset to a country with documented avian influenza A (H5N1) infections in poultry and/or humans. (For a regularly updated listing of H5N1-affected countries, see the OIE website at [http://www.oie.int/eng/en\\_index.htm](http://www.oie.int/eng/en_index.htm) and the WHO website at <http://www.who.int/en/> ).

*or*

Testing for avian influenza A (H5N1) should be considered on a case-by-case basis in consultation with state and local health departments for **hospitalized or ambulatory** patients with:

- Documented temperature of  $>100.4^{\circ}\text{F}$  ( $>38^{\circ}\text{C}$ ), *and*
- One or more of the following: cough, sore throat, or shortness of breath, *and*
- History of close contact either with poultry (e.g., visited a poultry farm, a household raising poultry, or a bird market) in an H5N1-affected country, or with a known or suspected human case of influenza A (H5N1) within 10 days prior to onset of symptoms.



## APPENDIX 3. REFERENCE TESTING GUIDELINES FOR POTENTIAL PANDEMIC STRAINS OF INFLUENZA

State and local laboratories may conduct initial testing on patient specimens for influenza A or potential highly pathogenic strains, if laboratory capacity is available. Due to the spread of avian influenza A (H5N1) in poultry in Asia, laboratories should be on the alert for avian and human H5 viruses. Procedures for diagnosis of human cases of influenza A (H5N1) are provided in Appendix 2. Influenza A viruses other than currently circulating H1 and H3 subtypes should also be considered as potentially pandemic if detected in humans.

- State/local laboratories should send specimens to CDC if:
  - A sample tested by the state or local laboratory is positive for H5 or another novel subtype;

**Note:** A laboratory should test for influenza A (H5) only if it is able to do so by PCR or has a BSL-3-enhanced facility for influenza A(H5) viral culture.

or

- A sample from a patient who meets the clinical and epidemiologic criteria for possible infection with a potentially pandemic virus is positive for influenza A by RT-PCR or rapid antigen detection,\* is negative for influenza A(H1) and A(H3), and the referring jurisdiction is not equipped to test for specific strains;

or

- The referring jurisdiction is not equipped to test samples for novel influenza viruses by RT-PCR and is requesting testing at CDC.

Shipping procedures for potential pandemic strains of influenza are provided in Appendix 5.

*\*Because the sensitivity of commercially available rapid diagnostic tests for influenza may not always be optimal, CDC will also accept specimens taken from persons who meet the clinical and epidemiological criteria even if they test negative by influenza rapid diagnostic testing—if PCR assays are not available at the state laboratory.*

## APPENDIX 4. LABORATORY BIOSAFETY GUIDELINES FOR HANDLING AND PROCESSING SPECIMENS OR ISOLATES OF NOVEL INFLUENZA STRAINS

### Key Messages

- Commercial antigen detection testing for influenza may be conducted under BSL-2 containment conditions if a Class II biological safety cabinet is used.
  - Clinical specimens from suspected novel influenza cases may be tested by RT-PCR using standard BSL-2 work practices in a Class II biological safety cabinet for initial processing of patient specimens.
  - If a specimen is confirmed positive for influenza A (H5N1) by RT-PCR, additional testing should be performed only under BSL-3 conditions with enhancements. CDC's Influenza Branch should be informed immediately by contacting the CDC Director's Emergency Operations Center (DEOC) at 770-488-7100.
  - A detailed description of recommended facilities, practices, and protective equipment for the various laboratory biosafety levels can be found in the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) manual at [www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm](http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm)
  - BSL-3 with enhancements and Animal Biosafety Level 3 include: all BSL-3 practices, procedures, and facilities, plus the use of negative-pressure, HEPA-filtered respirators or positive air-purifying respirators, and clothing change and personal showering protocols. Additional practices and/or restrictions may be added as conditions of USDA-APHIS permits. Registration of personnel and facilities with the Select Agent Program is required for work with highly pathogenic avian influenza (HPAI) viruses, which are classified as agricultural select agents.
- 
- State and local public health laboratories may test clinical specimens from suspected novel influenza cases by RT-PCR using standard BSL-2 work practices in a Class II biological safety cabinet. Commercial rapid antigen detection testing may also be conducted under BSL-2 biocontainment conditions.
  - Highly pathogenic avian influenza A (H5) and A (H7) viruses are classified as select agents. USDA regulations require that these viruses (as well as exotic low pathogenic avian influenza viruses) be handled under BSL-3 laboratory containment conditions, with enhancements (i.e., controlled-access double-door entry with change room and shower, use of respirators, decontamination of all wastes, and showering of all personnel). Laboratories that work with these viruses must be certified by USDA.
  - Laboratories should not perform virus isolation on respiratory specimens from patients who may be infected with an avian influenza virus unless stringent BSL-3 enhanced containment conditions can be met and diagnostic work can be kept separate from studies with other human influenza A viruses (i.e., H1 or H3). Therefore, respiratory virus cultures should not be performed in most clinical laboratories. Cultures for patients suspected of having influenza A (H5N1) infection should be sent only to state laboratories with appropriate BSL-3 with enhancement containment facilities or to CDC.

## APPENDIX 5. GUIDELINES FOR COLLECTING AND SHIPPING SPECIMENS FOR INFLUENZA DIAGNOSTICS

### Key Messages

- Appropriate specimens for influenza testing vary by type of test.
- Before collecting specimens, review the infection control precautions are described in Supplement 3.

## I. RESPIRATORY SPECIMENS<sup>4</sup>

Eight types of respiratory specimens may be collected for viral and/or bacterial diagnostics:

1) nasopharyngeal wash/aspirates, 2) nasopharyngeal swabs, 3) oropharyngeal swabs, 4) bronchoalveolar lavage, 5) tracheal aspirate, 6) pleural fluid tap, 7) sputum, and 8) autopsy specimens. Nasopharyngeal wash/aspirates are the specimen of choice for detection of most respiratory viruses and are the preferred specimen type for children aged <2 years.

Respiratory specimens for detection of most respiratory pathogens, and influenza in particular, are optimally collected within the first 3 days of the onset of illness. Before collecting specimens, review the infection control precautions in **Supplement 4**.

### A. Collecting specimens from the upper respiratory tract

#### 1. Nasopharyngeal wash/aspirate

- Have the patient sit with head tilted slightly backward.
- Instill 1 ml–1.5 ml of nonbacteriostatic saline (pH 7.0) into one nostril. Flush a plastic catheter or tubing with 2 ml–3 ml of saline. Insert the tubing into the nostril parallel to the palate. Aspirate nasopharyngeal secretions. Repeat this procedure for the other nostril.
- Collect the specimens in sterile vials. Label each specimen container with the patient's ID number and the date collected.
- If shipping domestically, use cold packs to keep the sample at 4°C. If shipping internationally, pack in dry ice (see shipping instructions below).

#### 2. Nasopharyngeal or oropharyngeal swabs

- Use only sterile dacron or rayon swabs with plastic shafts. Do **not** use calcium alginate swabs or swabs with wooden sticks, as they may contain substances that inactivate some viruses and inhibit PCR testing.
- To obtain a **nasopharyngeal swab**, insert a swab into the nostril parallel to the palate. Leave the swab in place for a few seconds to absorb secretions. Swab both nostrils.
- To obtain an **oropharyngeal swab**, swab the posterior pharynx and tonsillar areas, avoiding the tongue.
- Place the swabs immediately into sterile vials containing 2 ml of viral transport media. Break the applicator sticks off near the tip to permit tightening of the cap. Label each specimen container with the patient's ID number and the date the sample was collected.
- If shipping domestically, use cold packs to keep the sample at 4°C. If shipping internationally, pack in dry ice (see shipping instructions below).

<sup>4</sup> All types of respiratory specimens may be used in RT-PCR tests. Fresh-frozen unfixed tissue specimens may also be submitted for RT-PCR.

## B. Collecting specimens from the lower respiratory tract

### 1. Bronchoalveolar lavage, tracheal aspirate, or pleural fluid tap

- During bronchoalveolar lavage or tracheal aspirate, use a double-tube system to maximum shielding from oropharyngeal secretions.
- Centrifuge half of the specimen, and fix the cell pellet in formalin. Place the remaining unspun fluid in sterile vials with external caps and internal O-ring seals. If there is no internal O-ring seal, then seal tightly with the available cap and secure with Parafilm®. Label each specimen container with the patient's ID number and the date the sample was collected.
- If shipping domestically, use cold packs to keep the sample at 4°C. If shipping internationally, ship fixed cells at room temperature and unfixed cells frozen (see shipping instructions below).

### 2. Sputum

- Educate the patient about the difference between sputum and oral secretions.
- Have the patient rinse the mouth with water and then expectorate deep cough sputum directly into a sterile screw-cap sputum collection cup or sterile dry container.
- If shipping domestically, use cold packs to keep the sample at 4°C. If shipping internationally, pack in dry ice (see shipping instructions below).

## II. BLOOD COMPONENTS

Both acute and convalescent serum specimens should be collected for antibody testing. Collect convalescent serum specimens 2–4 weeks after the onset of illness. To collect serum for antibody testing:

- Collect 5 ml–10 ml of whole blood in a serum separator tube. Allow the blood to clot, centrifuge briefly, and collect all resulting sera in vials with external caps and internal O-ring seals. If there is no internal O-ring seal, then seal tightly with the available cap and secure with Parafilm®.
- The minimum amount of serum preferred for each test is 200 microliters, which can easily be obtained from 5 ml of whole blood. A minimum of 1 cc of whole blood is needed for testing of pediatric patients. If possible, collect 1 cc in an EDTA tube and in a clotting tube. If only 1cc can be obtained, use a clotting tube.
- Label each specimen container with the patient's ID number and the date the specimen was collected.
- If unfrozen and transported domestically, ship with cold packs to keep the sample at 4°C. If frozen or transported internationally, ship on dry ice.

## III. AUTOPSY SPECIMENS

CDC can perform immunohistochemical (IHC) staining for influenza A (H5) viruses on autopsy specimens. Viral antigens may be focal and sparsely distributed in patients with influenza, and are most frequently detected in respiratory epithelium of large airways. Larger airways (particularly primary and segmental bronchi) have the highest yield for detection of influenza viruses by IHC staining. Collection of the appropriate tissues ensures the best chance of detecting the virus by (IHC) stains.

- If influenza is suspected, a minimum total of 8 blocks or fixed-tissue specimens representing samples from each of the following sites should be obtained and submitted for evaluation:
  - Central (hilar) lung with segmental bronchi
  - Right and left primary bronchi
  - Trachea (proximal and distal)
  - Representative pulmonary parenchyma from right and left lung

In addition, representative tissues from major organs should be submitted for evaluation. In particular, for patients with suspected myocarditis or encephalitis, specimens should include myocardium (right and left ventricle) and CNS (cerebral cortex, basal ganglia, pons, medulla, and cerebellum). Specimens should be included from any other organ showing significant gross or microscopic pathology.

- Specimens may be submitted as:
  - Fixed, unprocessed tissue in 10% neutral buffered formalin, or
  - Tissue blocks containing formalin-fixed, paraffin-embedded specimens, or
  - Unstained sections cut at 3 microns placed on charged glass slides (10 slides per specimen)
- Specimens should be sent at room temperature (**NOT FROZEN**).
- Fresh-frozen unfixed tissue specimens may be submitted for RT-PCR.
- Include a copy of the autopsy report (preliminary, or final if available), and a cover letter outlining a brief clinical history and the submitter's full name, title, complete mailing address, phone, and fax numbers, in the event that CDC pathologists require further information. Referring pathologists may direct specific questions to CDC pathologists. The contact number for the Infectious Disease Pathology Activity is 404-639-3133, or the pathologists can be contacted 24 hours a day, 7 days a week through the CDC Emergency Response Hotline at 770-488-7100.

#### IV. SHIPPING INSTRUCTIONS

- State and local health departments should call the CDC Emergency Response Hotline (770-488-7100) before sending specimens for influenza A reference testing. This number is available 24 hours a day, 7 days a week. Hotline staff will notify a member of the Influenza Branch who will contact the health department to answer questions and provide guidance. In some cases, the state health department may arrange for a clinical laboratory to send samples directly to CDC.
- Specimens should be sent by Priority Overnight Shipping for receipt within 24 hours. Samples (such as fresh-frozen autopsy samples for RT-PCR or other clinical materials) may be frozen at -70 if the package cannot be shipped within a specified time (e.g., if the specimen is collected on a Friday but cannot be shipped until Monday).
- When sending clinical specimens, include the specimen inventory sheet (see below), include the assigned CDC case ID number, and note "Influenza surveillance" on all materials and specimens sent.

Include the CDC case ID number on all materials forwarded to CDC. Protocols for standard interstate shipment of etiologic agents should be followed, and are available at <http://www.cdc.gov/od/ohs/biosfty/shipregs.htm>. All shipments must comply with current DOT/IATA shipping regulations.

## V. INFLUENZA SPECIMEN INVENTORY SHEET

CDC CASE ID:

### List specimens sent to the CDC

Select a SOURCE\* from the following list for each specimen: Serum (acute), serum (convalescent), NP swab, NP aspirate/wash, bronchoalveolar lavage specimen (BAL), OP swab, tracheal aspirate, or tissue.

Specimen Type #1:

☐ Clinical Material

☐ Extracted RNA

☐ Virus Isolate

Source\*: \_\_\_\_\_

Collected :  $\frac{\text{m}}{\text{m}} / \frac{\text{d}}{\text{d}} / \frac{\text{y}}{\text{y}} \frac{\text{y}}{\text{y}} \frac{\text{y}}{\text{y}}$

Date Sent:  $\frac{\text{m}}{\text{m}} / \frac{\text{d}}{\text{d}} / \frac{\text{y}}{\text{y}} \frac{\text{y}}{\text{y}} \frac{\text{y}}{\text{y}}$

Specimen Type #2:

☐ Clinical Material

☐ Extracted RNA

☐ Virus Isolate

Source\*: \_\_\_\_\_

Collected :  $\frac{\text{m}}{\text{m}} / \frac{\text{d}}{\text{d}} / \frac{\text{y}}{\text{y}} \frac{\text{y}}{\text{y}} \frac{\text{y}}{\text{y}}$

Date Sent:  $\frac{\text{m}}{\text{m}} / \frac{\text{d}}{\text{d}} / \frac{\text{y}}{\text{y}} \frac{\text{y}}{\text{y}} \frac{\text{y}}{\text{y}}$

Specimen Type #3:

☐ Clinical Material

☐ Extracted RNA

☐ Virus Isolate

Source\*: \_\_\_\_\_

Collected :  $\frac{\text{m}}{\text{m}} / \frac{\text{d}}{\text{d}} / \frac{\text{y}}{\text{y}} \frac{\text{y}}{\text{y}} \frac{\text{y}}{\text{y}}$

Date Sent:  $\frac{\text{m}}{\text{m}} / \frac{\text{d}}{\text{d}} / \frac{\text{y}}{\text{y}} \frac{\text{y}}{\text{y}} \frac{\text{y}}{\text{y}}$

Specimen Type #4:

☐ Clinical Material

☐ Extracted RNA

☐ Virus Isolate

Source\*: \_\_\_\_\_

Collected :  $\frac{\text{m}}{\text{m}} / \frac{\text{d}}{\text{d}} / \frac{\text{y}}{\text{y}} \frac{\text{y}}{\text{y}} \frac{\text{y}}{\text{y}}$

Date Sent:  $\frac{\text{m}}{\text{m}} / \frac{\text{d}}{\text{d}} / \frac{\text{y}}{\text{y}} \frac{\text{y}}{\text{y}} \frac{\text{y}}{\text{y}}$

Specimen Type #5:

☐ Clinical Material

☐ Extracted RNA

☐ Virus Isolate

Source\*: \_\_\_\_\_

Collected :  $\frac{\text{m}}{\text{m}} / \frac{\text{d}}{\text{d}} / \frac{\text{y}}{\text{y}} \frac{\text{y}}{\text{y}} \frac{\text{y}}{\text{y}}$

Date Sent:  $\frac{\text{m}}{\text{m}} / \frac{\text{d}}{\text{d}} / \frac{\text{y}}{\text{y}} \frac{\text{y}}{\text{y}} \frac{\text{y}}{\text{y}}$

Carrier: \_\_\_\_\_ Tracking \_\_\_\_\_

## APPENDIX 6. RAPID DIAGNOSTIC TESTING FOR INFLUENZA

The following information in this appendix is designed to assist clinicians and clinical laboratory directors in the use of rapid diagnostic tests during interpandemic influenza seasons. During an influenza pandemic, one or more of these tests may be sensitive and specific enough to be used by clinicians to supplement clinical diagnoses of pandemic influenza. However, clinicians should be reminded that a negative test result might not rule out pandemic influenza and should not affect patient management or infection control decisions.

### I. INFORMATION FOR CLINICIANS

#### A. Background

Rapid diagnostic tests for influenza can help in the diagnosis and management of patients who present with signs and symptoms compatible with influenza. They also are useful for helping to determine whether institutional outbreaks of respiratory disease might be due to influenza. In general, rapid diagnostic testing for influenza should be done when the results will affect a clinical decision.

Rapid diagnostic testing can provide results within 30 minutes.

#### B. Reliability and interpretation of rapid test results

The reliability of rapid diagnostic tests depends largely on the conditions under which they are used. Understanding some basic considerations can minimize being misled by false-positive or false-negative results.

Median sensitivities of rapid diagnostic tests are generally ~70%–75% when compared with viral culture, but median specificities of rapid diagnostic tests for influenza are approximately 90%–95%. False-positive (and true negative) results are more likely to occur when disease prevalence in the community is low, which is generally at the beginning and end of the influenza season. False-negative (and true positive) results are more likely to occur when disease prevalence is high in the community, which is typically at the height of the influenza season.

#### C. Minimizing the occurrence of false results

- Use rapid diagnostic tests that have high sensitivity and specificity.
- Collect specimens as early in the illness as possible (within 4–5 days of symptom onset).
- Follow the manufacturer's instructions, including those for handling of specimens.
- Consider sending specimens for viral culture when:
  - Community prevalence of influenza is low and the rapid diagnostic test result is positive, or
  - Disease prevalence is high but the rapid diagnostic test result is negative.

(Contact your local or state health department for information about influenza activity.)

#### D. For further information

- Information about influenza is available at the CDC influenza website ([www.cdc.gov/flu](http://www.cdc.gov/flu)) or from the CDC Flu Information Line (800-CDC-INFO [English and Spanish]; 800-243-7889 [TTY]).
- For more information about influenza diagnostics, contact your state laboratory or state health department (<http://www.cdc.gov/other.htm#states>).
- Additional resources:
  - Association of Public Health Laboratories: [http://www.aphl.org/Public\\_Health\\_Labs/index.cfm](http://www.aphl.org/Public_Health_Labs/index.cfm)



- Weekly U.S. influenza activity reports: <http://www.cdc.gov/flu/weekly/fluactivity.htm>
- CDC Clinician Outreach and Communication Activity: <http://www.bt.cdc.gov/coca/index.asp>
- CDC website: <http://www.cdc.gov/flu/professionals/labdiagnosis.htm>

## II. INFORMATION FOR CLINICAL LABORATORY DIRECTORS

### A. Background

Rapid diagnostic tests for influenza are screening tests for influenza virus infection; they can provide results within 30 minutes. The use of commercial influenza rapid diagnostic tests by laboratories and clinics has increased substantially in recent years. At least ten rapid influenza tests have been approved by the U.S. Food and Drug Administration (FDA) (see Appendix 1).

Rapid tests differ in some important respects. Some can identify influenza A and B viruses and distinguish between them; some can identify influenza A and B viruses but cannot distinguish between them. Some tests are waived from requirements under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Most tests can be used with a variety of specimen types, but sensitivity and specificity can vary with specimen type. FDA approval is based upon specific specimen types.

Rapid tests vary in terms of sensitivity and specificity when compared with viral culture. Product insert information and research publications indicate that median sensitivities are approximately 70%–75% and median specificities are approximately 90%–95%.

Specimens to be used with rapid tests generally should be collected as close as possible to the start of symptoms and usually no more than 4–5 days later in adults. In very young children, influenza viruses can be shed for longer periods; therefore, in some instances, testing for a few days after this period may still be useful. Test sensitivity will be greatest in children, who generally have higher viral titers, if the specimen is obtained during the first 2 days of illness, and if the clinician or laboratory has more experience performing the test. The quality of the specimen tested also is critical for test sensitivity.

### B. Accuracy depends on disease prevalence

The positive and negative predictive values of rapid tests vary considerably depending on the prevalence of influenza in the community. False-positive (and true negative) influenza test results are more likely to occur when disease prevalence is low, which is generally at the beginning and end of the influenza season. False-negative (and true positive) influenza test results are more likely to occur when disease prevalence is high, which is typically at the height of the influenza season.

#### 1. Clinical considerations when influenza prevalence is low

When disease prevalence is low, the positive-predictive value (PPV) is low and false-positive test results are more likely. By contrast, the negative-predictive value (NPV) is high when disease prevalence is low, and negative results are more likely to be truly negative (see Graphs 1 and 2).

| If flu prevalence is... | and specificity is... | then PPV is...   | false-positive rate is... |
|-------------------------|-----------------------|------------------|---------------------------|
| VERY LOW (2.5%)         | POOR (80%)            | V. POOR (6%–12%) | V. HIGH (88%–94%)         |
| VERY LOW (2.5%)         | GOOD (98%)            | POOR (39%–56%)   | HIGH (44%–61%)            |
| MODERATE (20%)          | POOR (80%)            | POOR (38%–56%)   | HIGH (44%–62%)            |
| MODERATE (20%)          | GOOD (98%)            | GOOD (86%–93%)   | LOW (7%–14%)              |

Interpretation of positive results should take into account the clinical characteristics of the case-patient. If an important clinical decision is affected by the test result, the rapid test result should be confirmed by another test, such as viral culture or PCR.

## 2. Clinical considerations when influenza prevalence is high

When disease prevalence is relatively high, the NPV is low and false-negative test results are more likely. By contrast, when disease prevalence is high, the PPV is high and positive results are more likely to be true (see Graph 2).

| If flu prevalence is... | and sensitivity is... | then NPV is...     | false-negative rate is... |
|-------------------------|-----------------------|--------------------|---------------------------|
| MODERATE (20%)          | POOR (50%)            | MODERATE (86%–89%) | MODERATE (11%–14%)        |
| MODERATE (20%)          | HIGH (90%)            | V. GOOD (97%–99%)  | V. LOW (2%–3%)            |
| HIGH (40%)              | POOR (50%)            | MODERATE (70%–75%) | MODERATE (25%–30%)        |
| HIGH (40%)              | HIGH (90%)            | V. GOOD (93%–94%)  | LOW (6%–7%)               |

Interpretation of negative results should take into account the clinical characteristics of the case-patient. If an important clinical decision is affected by the test result, the rapid test result should be confirmed by another test, such as viral culture or PCR.

## C. Selecting tests

Selection of a test should take into consideration several factors, such as the types of specimens that are considered optimal for that test. Also, tests with high sensitivity and specificity will provide better positive and negative predictive values. Information about test characteristics is provided in product inserts and scientific articles and by the manufacturer.

## D. Changes in recommended procedures can affect test results

Modification by the user can affect test performances and increase false-positive and/or false-negative rates. Such modifications include using specimens for which the test is not optimized or using swabs that did not come with the rapid test kit (unless recommended).

## E. When are rapid diagnostic tests beneficial?

Use of rapid diagnostic tests are beneficial in these situations:

- To test cases during an outbreak of acute respiratory disease to determine if influenza is the cause, *or*
- To test selected patients during the influenza season, *or*
- In the fall or winter, to test selected patients presenting with respiratory illnesses compatible with influenza to help establish whether influenza is present in a specific population and to guide healthcare providers in diagnosing and treating respiratory illnesses.

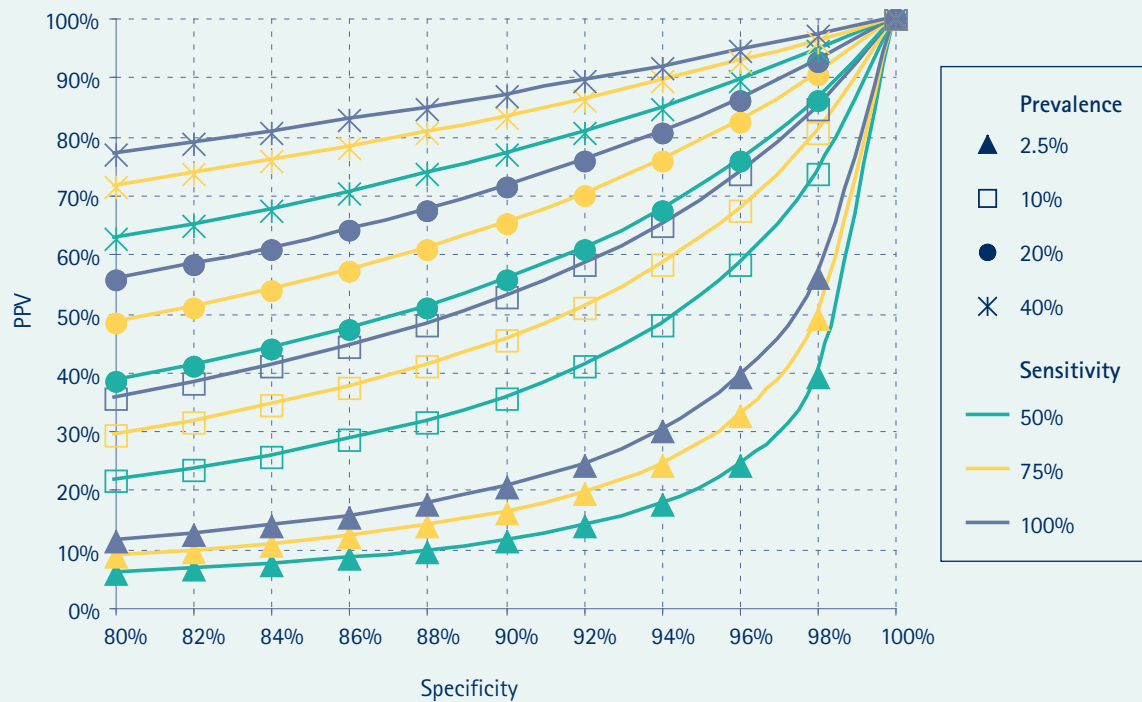
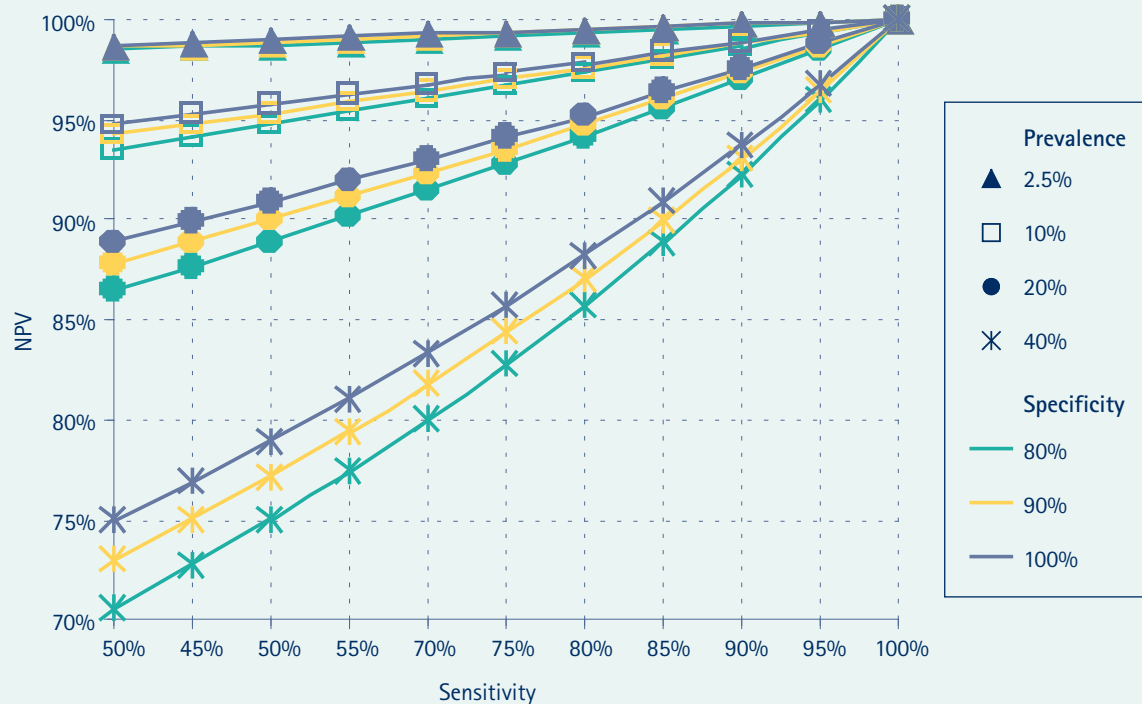
In general, the exclusive use of rapid tests does not address the public health need for obtaining viral isolates so that influenza virus strain subtyping and characterization can be conducted to monitor antigenic and genetic changes.

During an influenza pandemic, some rapid diagnostic tests may be able to detect the pandemic strain with adequate sensitivity and specificity. Rapid tests can be used by physicians to supplement clinical diagnoses of pandemic influenza.

Physicians should be reminded that a negative test result might not rule out influenza and should not affect patient management or infection control decisions.

## F. For further information

Information on influenza diagnostics is provided on the CDC website at: <http://www.cdc.gov/flu/professionals/labdiagnosis.htm>.

**GRAPH 1: IMPACT OF PREVALENCE, SENSITIVITY AND SPECIFICITY ON POSITIVE PREDICTIVE VALUE****GRAPH 2: IMPACT OF PREVALENCE, SENSITIVITY AND SPECIFICITY ON NEGATIVE PREDICTIVE VALUE**

## **APPENDIX 7. GUIDELINES FOR MEDICAL SURVEILLANCE OF LABORATORY RESEARCH PERSONNEL WORKING WITH NOVEL STRAINS OF INFLUENZA, INCLUDING AVIAN STRAINS AND OTHER STRAINS WITH PANDEMIC POTENTIAL**

### **Key Messages**

- Laboratory workers should receive training on the appropriate biosafety level for the type of work being performed.
- Before working with avian influenza A viruses, including highly pathogenic strains, laboratory workers should have a baseline serum sample obtained and stored for future reference.
- Workers in laboratories that contain avian influenza A viruses should report any fever or lower respiratory symptoms to their supervisors. Workers should be evaluated for possible exposures, and the clinical features and course of the illness should be closely monitored.
- Laboratory workers who are believed to have had a laboratory exposure to an avian influenza A virus or other highly pathogenic strain should be evaluated, counseled about the risk of transmission to others, and monitored for fever or lower respiratory symptoms as well as for any of the following: sore throat, rhinorrhea, chills, rigors, myalgia, headache, diarrhea.
- Local and/or state public health departments should be notified promptly of laboratory exposures and illnesses in exposed laboratory workers.

Medical surveillance of laboratory personnel can help to ensure that workers who are at risk of occupational exposure to avian influenza viruses or other novel animal or human influenza strains and who develop symptoms of illness receive appropriate medical evaluation and treatment, both for the benefit of their health and to prevent further transmission.

## **I. PREREQUISITES FOR WORKING WITH NOVEL AVIAN OR HUMAN INFLUENZA VIRUSES**

### **A. Baseline serum samples**

Before working with novel avian or human influenza viruses, laboratory workers should have a baseline serum sample obtained and stored for future reference.

### **B. Influenza vaccine**

Laboratories should offer the current inactivated influenza vaccine to laboratory personnel. Its use is especially encouraged for personnel working with avian viruses in BSL-3 enhanced laboratory conditions and for those who may be exposed to these viruses in the field. Immunization might reduce the chance of illness from exposure to human influenza viruses currently circulating in the community that could lead to confusion in monitoring for avian influenza A infection. Vaccines against novel influenza A viruses (e.g., H5N1) are undergoing clinical trials and might be available in the future.

### **C. Oseltamivir prophylaxis**

- It is not necessary to require oseltamivir for laboratory research personnel working with highly pathogenic influenza strains, but encourage it for those doing animal experiments only for the time they are working with animals and especially while working with ferrets.

- When considering oseltamivir prophylaxis, be sure to evaluate appropriate candidates for contraindications, answer their questions, review adverse effects, and explain the benefits.
- Maintain a log of persons on oseltamivir, persons evaluated and not on oseltamivir, doses dispensed, and adverse effects.
- Periodically evaluate and update oseltamivir policies and procedures.

## **D. Post-exposure prophylaxis**

Conditions for use of oseltamivir for post-exposure prophylaxis include a known or suspected laboratory exposure to live avian influenza virus, including highly pathogenic strains, for a person not on oseltamivir. Appropriate healthcare personnel should be available to evaluate immediately and dispense oseltamivir if the exposure occurs during working hours. If exposure occurs after working hours, an exposed laboratory person should present to the Emergency Department and, after evaluation, communicate with CDC for recommendations.

# **II. MANAGEMENT OF INFLUENZA-LIKE ILLNESS IN PERSONNEL WITH POSSIBLE EXPOSURE TO NOVEL AVIAN OR HUMAN INFLUENZA VIRUSES**

## **A. General procedures**

- Maintain a daily sign-in/out sheet to record name, date, time in/out, use of oseltamivir, and brief description of job tasks. This record will facilitate retrospective documentation if an illness occurs.
- Workers should report any influenza-like illness and any potential laboratory exposures to the supervisor (see also Supplement 4).

## **B. Evaluation and treatment**

### **1. During regular working hours**

- The affected employee should notify the supervisor. The supervisor should immediately contact the appropriate healthcare personnel and facility contacts (e.g., occupational health, infection control, or designee).
- Upon arrival at the designated clinic, the employee should be placed in a private room for isolation where a healthcare provider can provide consultation and evaluation.
- The healthcare provider should obtain a respiratory specimen (e.g. nasopharyngeal swab or aspirate) for viral culture. A rapid antigen test<sup>5</sup> with the ability to differentiate between influenza A and B should be used for initial diagnosis, followed by virus isolation.
- Based on: 1) the rapid test result (if influenza A positive), 2) the status of oseltamivir prophylaxis, and 3) the clinical evaluation, the healthcare provider should determine whether the patient will return to work, be sent home, or be sent to an infectious disease consultant.

### **2. During working hours when the employee calls from home**

- The employee should notify the supervisor. The supervisor should discuss the situation with the appropriate healthcare personnel and determine where and by whom the employee will be evaluated and specimens for viral culture will be obtained.

<sup>5</sup> If laboratory capacity is available, RT-PCR should be used to rule out the suspected pathogen.

- The employee may come to an on-site clinic for evaluation or may elect to see a personal physician. If the employee chooses to see a personal physician, the on-site clinician should discuss with the personal physician the likelihood of a laboratory-acquired infection. The personal physician should be asked to collect specimens for antigen detection and viral culture.
- An employee who is not sick enough to be admitted to a hospital should remain at home under the care of a personal physician, pending results from the viral culture. If influenza A (H3N2) or A (H1N1) is identified, the employee should be advised and can resume normal activities as soon as symptoms subside.
- If avian influenza A (e.g., H5, H7, H9) is identified, the family and other contacts should be monitored for illness.<sup>6</sup>
- Local public health officials should be notified about any confirmed avian influenza infections.

### 3. After working hours

- The employee should notify the supervisor. The supervisor should inform other persons as the situation dictates.
- If the employee is acutely ill with symptoms consistent with influenza, the employee and/or supervisor should contact the appropriate healthcare provider for instructions. The healthcare provider should conduct the initial evaluation and patient management.
- The supervisor should immediately ask the healthcare provider to collect specimens for rapid testing and viral culture.
- The employee should follow the advice of the healthcare provider with regard to further evaluation/treatment.

---

<sup>6</sup> Persons living with the ill person should be managed as described in Supplement 4.



# supplement 3

## healthcare planning

### TABLE OF CONTENTS

|                                                                                       |       |
|---------------------------------------------------------------------------------------|-------|
| SUMMARY OF ROLES AND RESPONSIBILITIES FOR HEALTHCARE AND PUBLIC HEALTH PARTNERS ..... | S3-2  |
| S3-I. RATIONALE .....                                                                 | S3-3  |
| S3-II. OVERVIEW .....                                                                 | S3-4  |
| S3-III. RECOMMENDATIONS FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS.....         | S3-4  |
| A. Planning for provision of care in hospitals.....                                   | S3-4  |
| 1. Planning process.....                                                              | S3-5  |
| 2. Planning elements.....                                                             | S3-5  |
| a) Hospital surveillance.....                                                         | S3-5  |
| b) Hospital communications.....                                                       | S3-6  |
| c) Education and training .....                                                       | S3-7  |
| d) Triage, clinical evaluation, and admission procedures .....                        | S3-8  |
| e) Facility access.....                                                               | S3-9  |
| f) Occupational health.....                                                           | S3-9  |
| g) Use and administration of vaccines and antiviral drugs.....                        | S3-10 |
| h) Surge capacity.....                                                                | S3-11 |
| i) Security .....                                                                     | S3-13 |
| j) Mortuary issues .....                                                              | S3-13 |
| B. Planning for provision of care in non-hospital settings.....                       | S3-13 |
| 1. Non-hospital healthcare facilities .....                                           | S3-14 |
| 2. Alternative care sites .....                                                       | S3-14 |
| S3-IV. RECOMMENDATIONS FOR THE PANDEMIC PERIOD .....                                  | S3-15 |
| A. Activating the facility's pandemic influenza response plan .....                   | S3-15 |
| 1. Pandemic influenza reported outside the United States .....                        | S3-15 |
| 2. Pandemic influenza reported in the United States .....                             | S3-15 |
| Box 1. Healthcare Facility Pandemic Influenza Planning Committee .....                | S3-16 |
| Box 2. Examples of Consumable and Durable Supply Needs .....                          | S3-17 |
| Table 1. Hospital Pandemic Influenza Triggers.....                                    | S3-18 |
| Appendix 1. Resources List for Healthcare Planning .....                              | S3-21 |
| Appendix 2. Hospital Preparedness Checklist.....                                      | S3-24 |



## **SUMMARY OF ROLES AND RESPONSIBILITIES FOR HEALTHCARE AND PUBLIC HEALTH PARTNERS**

### **INTERPANDEMIC AND PANDEMIC ALERT PERIODS**

#### **Healthcare facility responsibilities:**

- Develop planning and decision-making structures for responding to pandemic influenza.
- Develop written plans that address: disease surveillance, hospital communications, education and training, triage and clinical evaluation, facility access, occupational health, use and administration of vaccines and antiviral drugs, surge capacity, supply chain and access to critical inventory needs, and mortuary issues.
- Participate in pandemic influenza response exercises and drills, and incorporate lessons learned into response plans.

#### **State and local responsibilities:**

- Develop statewide and local or regional plans to manage an influenza pandemic.
- Assist healthcare facilities in conducting exercises and drills to test healthcare response issues and build partnerships among healthcare and public health officials, community leaders, and emergency response workers.
- Develop a communications infrastructure to facilitate and ensure the timely dissemination and transfer of information between the healthcare and public health sectors.
- Address legal issues that can affect staffing and patient care.

#### **HHS responsibilities:**

- Provide ongoing public health guidance on healthcare preparedness for an influenza pandemic.
- Provide healthcare facilities with model protocols for early detection and treatment of influenza among patients and staff; these protocols can be piloted during routine influenza seasons.

### **PANDEMIC PERIOD**

If an influenza pandemic begins in another country:

#### **Healthcare facility responsibilities:**

- Heighten institutional surveillance for influenza and prepare to activate institutional pandemic influenza plans, as necessary.

#### **State and local responsibilities:**

- Work with HHS to provide local physicians and hospital administrators with updated information and guidance as the situation unfolds.

## PANDEMIC PERIOD (CONT.)

If an influenza epidemic begins in or enters the United States:

### Healthcare facility responsibilities:

- Activate institutional pandemic influenza plans, in accordance with the "Hospital Pandemic Influenza Triggers" outlined in Table 1.
- Identify and isolate all potential patients with pandemic influenza.
  - Implement infection control practices to prevent influenza transmission.
  - Ensure rapid and frequent communication within healthcare facilities and between healthcare facilities and health departments.
- Implement surge-capacity plans to sustain healthcare delivery.

### State and local health responsibilities:

- Provide healthcare facilities with information on the global, national, and local situation.
- Work with HHS to provide guidance (as needed) on infection control measures for healthcare and non-healthcare settings.
- Work with healthcare facilities to address surge capacity needs.

### HHS responsibilities:

- Assist state and local healthcare and public health partners on issues related to hospital infection control, occupational health, antiviral drug use and clinical management, vaccination, and medical surge capacity.
- Provide states with materials from the Strategic National Stockpile for further distribution to healthcare facilities.

## S3-I. RATIONALE

An influenza pandemic will place a huge burden on the U.S. healthcare system. Published estimates based on extrapolation of the 1957 and 1968 pandemics suggest that there could be 839,000 to 9,625,000 hospitalizations, 18–42 million outpatient visits, and 20–47 million additional illnesses, depending on the attack rate of infection during the pandemic.<sup>1</sup> Estimates based on extrapolation from the more severe 1918 pandemic suggest that substantially more hospitalizations and deaths could occur. The demand for inpatient and intensive-care unit (ICU) beds and assisted ventilation services could increase by more than 25% under the less severe scenario. Pre-pandemic planning by healthcare facilities is therefore essential to provide quality, uninterrupted care to ill persons and to prevent further spread of infection. Effective planning and implementation will depend on close collaboration among state and local health departments,<sup>2</sup> community partners, and neighboring and regional healthcare facilities. Despite planning and preparedness, however, in a severe pandemic it is possible that shortages, for example of mechanical ventilators, will occur and medical care standards may need to be adjusted to most effectively provide care and save as many lives as possible.

<sup>1</sup> Meltzer et al, EID 2004 Meltzer MI, Cox NJ, Fukuda K The economic impact of pandemic influenza in the United States: priorities for intervention. EID 1999 Sep-Oct;5(5):659-71.

<sup>2</sup> Depending on the locality, health departments may also include territorial or tribal health departments.

## S3-II. OVERVIEW

Supplement 3 provides healthcare partners with recommendations for developing plans to respond to an influenza pandemic. The focus is on planning during the Interpandemic Period for: pandemic influenza surveillance, decision-making structures for responding to a pandemic, hospital communications, education and training, patient triage, clinical evaluation and admission, facility access, occupational health, distribution of vaccines and antiviral drugs, surge capacity, and mortuary issues. Planning for the provision of care in non-hospital settings—including residential care facilities, physicians' offices, private home healthcare services, emergency medical services, federally qualified health centers (FQHCs),<sup>3</sup> rural health clinics, and alternative care sites—is also addressed.

The recommendations for the Pandemic Period focus on activation of institutional pandemic influenza response plans. The ability to provide detailed guidance on this aspect of the pandemic is limited because of uncertainty about how the pandemic will evolve and variation and uncertainty of local factors that will influence decisions at various stages.

The activities suggested in Supplement 3 are intended to be synergistic with those of other pandemic influenza planning efforts, including state preparedness plans. Links to additional resources that provide the most up-to-date guidance on particular topics are included. A checklist to help facilities assess their current level of readiness to deal locally with an influenza pandemic is provided in Appendix 2.

## S3-III. RECOMMENDATIONS FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS

### A. Planning for provision of care in hospitals

U.S. healthcare facilities must be prepared for the rapid pace and dynamic characteristics of pandemic influenza. All hospitals should be equipped and ready to care for: 1) a limited number of patients infected with a pandemic influenza virus, or other novel strains of influenza, as part of normal operations; and 2) a large number of patients in the event of escalating transmission of pandemic influenza.

Hospital response plans for pandemic influenza should:

- Outline administrative measures for detecting the introduction of pandemic influenza, preventing its spread, and managing its impact on the facility and the staff.
- Build on existing preparedness and response plans for bioterrorism events, SARS, and other infectious disease emergencies.
- Incorporate planning suggestions from state and local health departments and other local and regional healthcare facilities and response partners.
- Identify criteria and methods for measuring compliance with response measures (e.g., infection control practices, case reporting, patient placement, healthcare worker illness surveillance).
- Review and update inventories of supplies that will be in high demand during an influenza pandemic.
- Review procedures for the receipt, storage, and distribution of assets received from federal stockpiles.
- Include mechanisms for periodic reviews and updates.

<sup>3</sup> A federally qualified health center (FQHC) is a type of provider defined by the Medicare and Medicaid statutes. FQHCs include health centers receiving grants under section 330 of the Public Health Service Act, certain tribal organizations, and clinics designated by HHS as FQHC Look-Alikes. More information may be found at: <http://www.cms.hhs.gov/providers/fqhc/>

Hospitals that intend to use an “all-hazards” incident command structure for responding to pandemic influenza will need to incorporate the relevant aspects of communicable disease control that are included in this supplement and in **Supplement 4**. Hospitals should consider using “table top” simulations or other exercises to test response capabilities (see Appendix 1).

## 1. Planning process

- Groups and individuals involved in the hospital planning process should include:
  - An internal, multidisciplinary planning committee with responsibility for pandemic influenza preparedness and response. The committee should include technical experts, persons with decision-making authority, and representatives from a range of response partners (see Box 1). A pre-existing all-hazards preparedness team (e.g., established for bioterrorism or SARS response) might assume this role.
  - A response coordinator/incident commander to direct the facility's planning and response efforts
  - A core group from the multidisciplinary planning committee to work with the response coordinator and assist with decision-making during the pandemic
- The pandemic influenza response team should plan to remain active throughout the pandemic period, which could be several weeks or months.
- Hospital planning for pandemic influenza should consider concurrent public health, community, and healthcare planning efforts at the local, state, and regional levels. Some possible mechanisms for collaboration and coordination are to:
  - Include a state or local health department representative as an ex officio member on the hospital planning committee (see Box 1).
  - Obtain copies of draft pandemic influenza plans from other local or regional hospitals to use as models.
  - Work with other local hospitals, community organizations (e.g., social service groups), and the state or local health department to coordinate healthcare activities in the community and define responsibilities for each entity during a pandemic.
  - Collaborate with HRSA hospital preparedness programs in the state or region.
  - Include a hospital representative in local or regional planning efforts.
  - Include representatives from safety-net providers<sup>4</sup> in the local community (e.g., FQHCs and rural health clinics).

## 2. Planning elements

The elements of a hospital influenza pandemic preparedness plan discussed below are listed in the Hospital Preparedness Checklist provided in Appendix 2.

### a) Hospital surveillance

- **Hospital surveillance for novel strains of influenza**  
During the Interpandemic and Pandemic Alert Periods, healthcare providers and healthcare facilities play an essential role in surveillance for suspected cases of infection with novel strains of influenza and should be on the alert for such cases. Novel strains may include avian or animal influenza strains that can infect humans (like avian influenza A

<sup>4</sup> Health care safety net providers deliver care to low-income and other vulnerable populations, including the uninsured and those covered by Medicaid. Many of these providers have either a legal mandate or an explicit policy to provide services regardless of a patient's ability to pay (<http://www.ahcpr.gov/data/safetynet/faq.htm>). Major safety net providers include public hospitals and community health centers as well as teaching and community hospitals, and private physicians.

[H5N1]) and new or re-emergent human viruses that cause cases or clusters of human disease. For detection of cases during the Interpandemic and Pandemic Alert Periods, hospitals should have:

- Procedures in place to facilitate laboratory testing on-site using proper biosafety levels and reporting of unusual influenza isolates through local and state health department channels (see **Supplement 1**). If appropriate methods or biosafety levels do not exist at the hospital, specimens should be shipped to the state health department.
- Predetermined thresholds for activating pandemic influenza surveillance plans (see S3-III.A and the Table).
- **Hospital surveillance for pandemic influenza**  
During the Pandemic Period, healthcare providers and healthcare facilities will play an essential role in pandemic influenza surveillance (see **Supplement 1**). For detection of cases during the Pandemic Period, hospitals should have:
  - Mechanisms for conducting surveillance in emergency departments to detect any increases in influenza-like illness (see box below) during the early stages of the pandemic
  - Mechanisms for monitoring employee absenteeism for increases that might indicate early cases of pandemic influenza
  - Mechanisms for tracking emergency department visits and hospital admissions and discharge of suspected or laboratory-confirmed pandemic influenza patients. This information will be needed to: 1) support local public health personnel in monitoring the progress and impact of the pandemic, 2) assess bed capacity and staffing needs, and 3) detect a resurgence in pandemic influenza that might follow the first wave of cases.
  - Updated information on the types of data that should be reported to state or local health departments (e.g., admissions; discharges/deaths; patient characteristics such as age, underlying disease, and secondary complications; illnesses in healthcare personnel) and plans for how these data will be collected during a pandemic. State and local health departments will provide guidance on the scope and mechanism of reporting (see **Supplement 1**).
  - Criteria for distinguishing pandemic influenza from other respiratory diseases (see **Supplement 5**).

Symptoms of influenza include fever, headache, myalgia, prostration, coryza, sore throat, and cough. Nausea and vomiting are also commonly reported among children. Typical influenza (or “flu-like”) symptoms, such as fever, may not always be present in elderly patients, young children, patients in long-term care facilities, or persons with underlying chronic illnesses (see **Supplement 5**, Box 2).

#### b) Hospital communications

Each hospital should work with public health officials, other government officials, neighboring healthcare facilities, the lay public, and the press to ensure rapid and ongoing information-sharing during an influenza pandemic.

- **External communications**
  - Assign responsibility for external communication about pandemic influenza; identify a person responsible for updating public health reporting (e.g., infection control), a clinical spokesperson (e.g., medical director), and a media spokesperson (e.g., public information officer).
  - Identify points of contact among local media (e.g., newspaper, radio, television) representatives and public officials and community leaders.
  - With guidance from state or local health departments, determine the methods, frequency, and scope of external communications.
  - Determine how communications between local and regional healthcare facilities will be handled.

- Consult with state or local health departments on plans for coordinating or facilitating communication among healthcare facilities. In the absence of such a plan, consider organizing a meeting of local health facilities to determine an optimal communications strategy.
- Identify key topics for ongoing communication (e.g., staffing needs, bed capacity, durable and consumable medical equipment and device needs, supplies of influenza vaccine and antiviral drugs).
- Assign responsibility within the hospital for communications with other healthcare facilities.
- Consult with local or state public health officials regarding the hospital's role in communicating with the media and the public.
- Determine the type of hospital-specific communications (e.g., press releases, community bulletin board) that might be needed, and develop templates for these materials.
- Consult with local or state health departments on plans for a pandemic influenza hotline and/or website for public inquiries.
  - Determine how public inquiries will be handled (e.g., refer callers to the health department; provide technical support for handling calls).
  - Identify the types of information that will be provided by the hospital and the types of inquiries that will be referred to state or local health departments.
- **Internal communications**
  - Determine how to keep administrators, personnel (including infection control staff and intake and triage staff), patients, and visitors informed of the ongoing impact of pandemic influenza on the facility and on the community.

### c) Education and training

Each hospital should develop an education and training plan that addresses the needs of staff, patients, family members, and visitors. Hospitals should assign responsibility for coordination of the pandemic influenza education and training program and identify training materials—in different languages and at different reading levels, as needed—from HHS agencies, state and local health departments, and professional associations (see Appendix 1).

- **Staff Education**
  - Identify educational resources for clinicians, including federally sponsored teleconferences, state and local health department programs, web-based training materials, and locally prepared presentations.
  - General topics for staff education should include:
    - Prevention and control of influenza
    - Implications of pandemic influenza
    - Benefits of annual influenza vaccination
    - Role of antiviral drugs in preventing disease and reducing rates of severe influenza and its complications
    - Infection control strategies for the control of influenza, including respiratory hygiene/cough etiquette, hand hygiene, standard precautions, droplet precautions, and, as appropriate, airborne precautions (see Supplement 4).
  - Hospital-specific topics for staff education should include:
    - Policies and procedures for the care of pandemic influenza patients, including how and where pandemic influenza patients will be cohorted
    - Pandemic staffing contingency plans, including how the facility will deal with illness in personnel

- Policies for restricting visitors and mechanisms for enforcing these policies
- Reporting to the health department suspected cases of infection caused by novel influenza strains during the Interpandemic and Pandemic Alert Periods
- Measures to protect family and other close contacts from secondary occupational exposure
- Establish a schedule for training/education of clinical staff and a mechanism for documenting participation. Consider using annual infection control updates/meetings, medical Grand Rounds, and other educational venues as opportunities for training on pandemic influenza.
- Cross-train clinical personnel, including outpatient healthcare providers, who can provide support for essential patient-care areas (e.g., emergency department, ICU, medical units).
- Train intake and triage staff to detect patients with influenza symptoms and to implement immediate containment measures to prevent transmission (see also **Supplement 5**).
- Supply social workers, psychologists, psychiatrists, and nurses with guidance for providing psychological support to patients and hospital personnel during an influenza pandemic (see **Supplement 11**). (HHS agencies will identify or develop educational materials on: signs of distress, traumatic grief, stress management and effective coping strategies, building and sustaining personal resilience, and behavioral and psychological support resources.) If feasible, hospitals should also provide psychological-support training to appropriate individuals who are not mental health professionals (e.g., primary-care clinicians, leaders of community and faith-based organizations).
- Develop a strategy for "just-in-time" training of non-clinical staff who might be asked to assist clinical personnel (e.g., help with triage, distribute food trays, transport patients), students, retired health professionals, and volunteers who might be asked to provide basic nursing care (e.g., bathing, monitoring of vital signs); and other potential in-hospital caregivers (e.g., family members of patients).
- **Education of patients, family members, and visitors**  
Patients and others should know what they can do to prevent disease transmission in the hospital, as well as at home and in community settings.
  - Identify language-specific and reading-level appropriate materials for educating patients, family members, and hospital visitors during an influenza pandemic. If language-specific materials are not available for the population(s) being served, arrange for translations.
  - Develop a plan for distributing information to all persons who enter the hospital. Identify staff to answer questions about procedures for preventing influenza transmission.

#### d) Triage, clinical evaluation, and admission procedures

During the peak of a pandemic, hospital emergency departments and outpatient offices might be overwhelmed with patients seeking care. Therefore, triage should be conducted to: 1) identify persons who might have pandemic influenza, 2) separate them from others to reduce the risk of disease transmission, and 3) identify the type of care they require (i.e., home care or hospitalization) (see **Supplement 5**).

- Develop a strategy for triage, diagnosis, and isolation of possible pandemic influenza patients. Consider the following triage mechanisms:
  - Using phone triage to identify patients who need emergency care and those who can be referred to a medical office or other non-urgent facility
  - Assigning separate waiting areas for persons with respiratory symptoms
  - Assigning a separate triage evaluation area for persons with respiratory symptoms



- Assigning a “triage coordinator” to manage patient flow, including deferring or referring patients who do not require emergency care (see **Supplement 4** and **Supplement 5**).
- Review procedures for the clinical evaluation of patients in the emergency department and in outpatient medical offices to facilitate efficient and appropriate disposition of patients.
- Review admission procedures and streamline them as needed to limit the number of patient encounters in the hospital (e.g., direct admission to an inpatient bed).
- Identify a “trigger” point at which screening for signs and symptoms of pandemic influenza in all persons entering the hospital will escalate from passive (e.g., signs at the entrance) to active (e.g., direct questioning). In addition to visual alerts, potential screening measures might include priority triage of persons with respiratory symptoms and telephone screening of patients with appointments.

#### e) Facility access

Hospitals should determine in advance the criteria and procedures they will use to limit access to the facility if pandemic influenza spreads through the community.

- Define “essential” and “non-essential” visitors with regard to the hospital and the population served. Develop protocols for limiting non-essential visitors.
- Develop criteria or “triggers” for temporary closing of the hospital to new admissions and transfers. The criteria should consider staffing ratios, isolation capacity, and risks to non-influenza patients. As part of this effort, hospital administrators should: 1) determine who will make decisions about temporary closings and how and to whom these decisions will be communicated, and 2) consult with state and local health departments on their roles in determining policies for hospital admissions and transfers.
- Determine how to involve hospital security services in enforcing access controls. Consider meeting with local law enforcement officials in advance to determine what assistance, if any, they can provide. Note that local law enforcement might be overburdened during a pandemic and have limited ability to assist healthcare facilities with security services.

#### f) Occupational health

The ability to deliver quality health care is dependent on adequate staffing and optimum health and welfare of staff. During a pandemic,<sup>5</sup> the healthcare workforce will be stressed physically and psychologically. Like others in the community, many healthcare workers will become ill. Healthcare facilities must be prepared to: 1) protect healthy workers from exposures in the healthcare setting through the use of recommended infection control measures; 2) evaluate and manage symptomatic and ill healthcare personnel; 3) distribute and administer antiviral drugs and/or vaccines to healthcare personnel, as recommended by HHS and state health departments; and 4) provide psychosocial services to health care workers and their families to help sustain the workforce.

- **Managing ill workers**
  - Establish a plan for detecting signs and symptoms of influenza in healthcare personnel before they report for duty.
  - Develop policies for managing healthcare workers with respiratory symptoms that take into account HHS recommendations for healthcare workers with influenza (see [www.cdc.gov/ncidod/hip/GUIDE/infectcont98.htm](http://www.cdc.gov/ncidod/hip/GUIDE/infectcont98.htm))
  - Consider assigning staff who are recovering from influenza to care for influenza patients.

<sup>5</sup> During the Pandemic Alert Period, healthcare personnel exposed to avian influenza A (H5N1) or other novel strains of influenza should be managed on a case-by-case basis (see **Supplement 5**).

- **Time-off policies**

Ensure that time-off policies and procedures consider staffing needs during periods of clinical crisis.

- **Reassignment of high-risk personnel**

Establish a plan to protect personnel at high risk for complications of influenza (e.g., pregnant women, immunocompromised persons) by reassigning them to low-risk duties (e.g., non-influenza patient care, administrative duties that do not involve patient care) or placing them on furlough.

- **Psychosocial health services** (see also Supplement 11)

- Identify mental health and faith-based resources for counseling of healthcare personnel during a pandemic. Counseling should include measures to maximize professional performance and personal resilience by addressing management of grief, exhaustion, anger, and fear; physical and mental health care for oneself and one's loved ones; and resolution of ethical dilemmas.
- Determine a strategy for supporting healthcare workers' needs for rest and recuperation.
- Develop a strategy for housing and feeding healthcare personnel who might be needed on-site for prolonged periods
- Develop a strategy for accommodating and supporting staff who have child- or elder-care responsibilities.

- **Influenza vaccination and use of antiviral drugs**

- Promote annual influenza vaccination among hospital employees. Increased vaccination coverage during the Interpandemic Period might help increase vaccine acceptance during a pandemic and will limit the spread of seasonal influenza.
- Ensure that a system is in place for documenting influenza vaccination of healthcare personnel. The hospital might decide to enroll in the National Healthcare Safety Network (NHSN; [www.cdc.gov/ncidod/hip/NNIS/members/nhsn.htm](http://www.cdc.gov/ncidod/hip/NNIS/members/nhsn.htm)) to help track employee vaccination and health status.
- Establish a strategy for rapidly vaccinating or providing antiviral prophylaxis or treatment to healthcare personnel as recommended by HHS and state health departments. Preliminary recommendations on the use of antiviral drugs and vaccination have been established (see Part 1, Appendix E and Supplement 6 and Supplement 7) but will need to be tailored to fit the epidemiology of the pandemic.

#### g) **Use and administration of vaccines and antiviral drugs**

- **Pandemic influenza vaccine and "pre-pandemic" influenza vaccine**

Once the characteristics of a new pandemic influenza virus are identified, the development of a pandemic vaccine will begin. Recognizing that there may be benefits to immunization with a vaccine prepared before the pandemic against an influenza virus of the same subtype, efforts are underway to stockpile vaccines for subtypes with pandemic potential. As supplies of these vaccines become available, it is possible that some healthcare personnel and others critical to a pandemic response will be recommended for vaccination to provide partial protection or immunological priming for a pandemic strain. Policies for the use of pre-pandemic vaccine have not been finalized.

- Interim recommendations on priority groups for vaccination and strategies for vaccine distribution are discussed in Supplement 6. During a pandemic, these recommendations will be updated, taking into account populations which are most at risk. In the interim, healthcare facilities should:
  - Monitor updated HHS information and recommendations on the development, distribution, and use of a pandemic influenza vaccine (<http://www.pandemicflu.gov>)
  - Work with local and state health departments on plans for distributing pandemic influenza vaccine.
  - Provide estimates of the quantities of vaccine needed for hospital staff and patients, as requested by the state health department.

- Develop a stratification scheme for prioritizing vaccination of healthcare personnel who are most critical for patient care and essential personnel to maintain the day-to-day operation of the healthcare facility.
- Develop a pandemic influenza vaccination plan in the hospital.
- **Antiviral drugs**  
Antiviral drugs effective against the circulating pandemic strain can be used for treatment and possibly prophylaxis during an influenza pandemic. Because of the effectiveness of treatment with antiviral drugs such as oseltamivir and zanamivir, and the greater efficiency of treatment in a setting of limited supply, the use of prophylaxis will be restricted to maximize health benefits. Interim recommendations for the use of antiviral drugs are discussed in **Supplement 7**. Healthcare facilities should consider how antiviral drugs might be used in their patient and healthcare worker populations, taking into account state and national guidelines, and determine if a reserve supply should be stockpiled. (See also HRSA cooperative agreements [www.hrsa.gov/grants/preview/guidancespecial/hrsa05001.htm](http://www.hrsa.gov/grants/preview/guidancespecial/hrsa05001.htm).)

#### h) Surge capacity

Healthcare facilities should plan ahead to address emergency staffing needs and increased demand for isolation wards, ICUs, assisted ventilation services, and consumable and durable medical supplies (Box 2). Hospital planners can use FluSurge software (<http://www.cdc.gov/flu/flusurge.htm>) to estimate the potential impact of a pandemic on resources such as staffed beds (both overall and ICU) and ventilators (see also HRSA and AHRQ planning and surge capacity resources listed in Appendix 1.)

- **Staffing**
  - Assign responsibility for the assessment and coordination of staffing during an emergency.
  - Estimate the minimum number and categories of personnel needed to care for a single patient or a small group of patients with influenza complications on a given day.
  - Determine how the hospital will meet staffing needs as the number of patients with pandemic influenza increases and/or healthcare and support personnel become ill or remain at home to care for ill family members. Consider the following options:
    - Assigning patient-care responsibilities to clinical administrators
    - Recruiting retired healthcare personnel
    - Using trainees (e.g., medical and nursing students)
    - Using patients' family members in an ancillary healthcare capacity
  - Collaborate with local and regional healthcare-planning groups in an attempt to achieve adequate staffing of the hospital during an influenza pandemic (e.g., decide whether and how staff will be shared with other healthcare facilities, determine how salary issues will be addressed for employees shared between facilities, and consider ways to increase the number of home healthcare staff to reduce hospital admissions during the emergency). State and local health departments can help assess the feasibility of recruiting staff from different hospitals and/or regions, working in coordination with federal facilities, including Veterans Administration and Department of Defense hospitals. Healthcare facilities may implement these arrangements through Mutual Aid Agreements (MAAs) or Memoranda of Understanding/Agreement (MOU/As).
  - Increase cross-training of personnel to provide support for essential patient-care areas at times of severe staffing shortages (e.g., in emergency departments, ICUs, or medical units) (see also S3-III.A.2.c).
  - Create a list of essential-support personnel titles (e.g., environmental and engineering services, nutrition and food services, administrative, clerical, medical records, information technology, laboratory) that are needed to maintain hospital operations.

- Create a list of non-essential positions that can be re-assigned to support critical hospital services or placed on administrative leave to limit the number of persons in the hospital.
- Consult with the state health department<sup>6</sup> on plans for rapidly credentialing healthcare professionals during a pandemic. This might include defining when an "emergency staffing crisis" can be declared and identifying emergency laws that allow employment of healthcare personnel with out-of-state licenses.
- Identify insurance and liability issues related to the use of non-facility staff.
- Explore opportunities for recruiting healthcare personnel from other healthcare settings, (e.g., medical offices and day-surgery centers). Consult public health partners about existing state or local plans for recruitment and deployment of local personnel.
- **Bed capacity**
  - Review and revise admissions criteria for times when bed capacity is limited (see also S3-III.A.2.e).
  - Develop policies and procedures for expediting the discharge of patients who do not require ongoing inpatient care (e.g., develop plans and policies for transporting discharged patients home or to other facilities; create a patient discharge holding area or discharge lounge to free up bed space).
  - Work with home healthcare agencies to arrange at-home follow-up care for patients who have been discharged early and for those whose admission was deferred because of limited bed space.
  - Develop criteria or "triggers" for temporarily canceling elective surgical procedures and determining what and where emergency procedures will be performed during a pandemic. Determine which elective procedures will be temporarily postponed.
  - Determine whether patients who require emergency procedures will be transferred to another hospital.
  - Discuss with local and state health departments how bed availability, including available ICU beds and ventilators, will be tracked during a pandemic.
  - Consult with hospital licensing agencies on plans and processes to expand bed capacity during times of crisis. These efforts should take into account the need to provide staff and medical equipment and supplies to care for the occupant of each additional hospital bed.
  - Discuss with healthcare regulators whether, how, and when an "Altered Standards of Care in Mass Casualty Events" will be invoked and applied to pandemic influenza (See <http://www.ahrq.gov/research/altstand/>).
  - Develop policies and procedures for shifting patients between nursing units to free up bed space in critical-care areas and/or to cohort pandemic influenza patients.
  - Develop Mutual Aid Agreements (MAAs) or Memoranda of Understanding/Agreement (MOU/As) with other local facilities who can accept non-influenza patients who do not need critical care.
  - Identify areas of the facility that could be vacated for use in cohorting influenza patients. Consider developing criteria for shifting use of available space based on ability to support patient-care needs (e.g., access to bathroom and shower facilities). Consider developing cohorting protocols based on a patient's stage of recovery and infectivity.
- **Consumable and durable supplies**
  - Evaluate the existing system for tracking available medical supplies in the hospital to determine whether it can detect rapid consumption, including items that provide personal protection (e.g., gloves, masks). Improve the system as

<sup>6</sup> The HRSA Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) is helping each state and territory establish a standardized volunteer registration system. Additional information is available at: [www.hrsa.gov/bioterrorism/esarvhp/](http://www.hrsa.gov/bioterrorism/esarvhp/). Two new draft standards on emergency credentialing have been offered for public comment by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO; <http://www.jcaho.org/>).

needed to respond to growing demands for resources during an influenza pandemic (<http://www.cdc.gov/flu/fluurge.htm>).

- Consider stockpiling enough consumable resources such as masks (see Box 2) for the duration of a pandemic wave (6–8 weeks).
- Assess anticipated needs for consumable and durable resources, and determine a trigger point for ordering extra resources. Estimate the need for respiratory care equipment (including mechanical ventilators), and develop a strategy for acquiring additional equipment if needed. Neighboring hospitals might consider developing inventories of equipment and determining whether and how that equipment might be shared during a pandemic.
- Anticipate needs for antibiotics to treat bacterial complications of influenza, and determine how supplies can be maintained during a pandemic (see Supplement 5).
- Establish contingency plans for situations in which primary sources of medical supplies become limited. Consult with the local and state health departments about access to the national stockpile during an emergency.
- **Continuation of essential medical services**
  - Address how essential medical services will be maintained for persons with chronic medical problems served by the hospital (e.g., hemodialysis patients).
  - Develop a strategy for ensuring uninterrupted provision of medicines to patients who might not be able to (or should not) travel to hospital pharmacies.

#### i) Security

Healthcare facilities should plan for additional security. This may be required given the increased demand for services and possibility of long wait times for care, and because triage or treatment decisions may lead to people not receiving the care they think they require.

#### j) Mortuary issues

To prepare for the possibility of mass fatalities during an influenza pandemic, hospitals should do the following:

- Assess current capacity for refrigeration of deceased persons.
- Discuss mass fatality plans with local and state health officials and medical examiners.
- Work with local health officials and medical examiners to identify temporary morgue sites.
- Determine the scope and volume of supplies (e.g., body bags) needed to handle an increased number of deceased persons.

Resources for addressing these issues are provided in Appendix 1.

## B. Planning for provision of care in non-hospital settings

Planning and effective delivery of care in outpatient settings is critical. Appropriate management of outpatient influenza cases will reduce progression to severe disease and thereby reduce demand for inpatient care. A system of effective outpatient management will have several components. To decrease the burden on providers and to lessen exposure of the “worried well” to persons with influenza, telephone hotlines should be established to provide advice on whether to stay home or to seek care. Most persons who seek care can be managed appropriately by outpatient providers. Health care networks may designate specific providers, offices, or clinics for patients with influenza-like illness. Nevertheless, some persons with influenza will likely present to all medical offices and clinics so that planning and preparedness is important at every outpatient care site. In underserved areas, health departments may establish influenza clinics to facilitate access. Hospitals should develop a strategy for triage of potential influenza patients, which may include establishing a site outside of the Emergency Department

where persons can be seen initially and identified as needing emergency care or may be referred to an outpatient care site for diagnosis and management. Finally, home health care providers and organizations can provide follow-up for those managed at home, decreasing potential exposure of the public to persons who are ill and may transmit infection

Effective management of outpatient care in communities will require that health departments, health care organizations, and providers communicate and plan together. Issues to address include:

- Plan to establish and staff telephone hotlines.
- Develop training modules, protocols and algorithms for hotline staff.
- Within health care networks, develop plans on the organization of care for influenza patients and develop materials and strategies to inform patients on care-seeking during a pandemic
- For clinics and offices, develop plans that include education, staffing, triage, infection control in waiting rooms and other areas, and communication with healthcare partners and public health authorities.

## 1. Non-hospital healthcare facilities

The hospital planning recommendations (see S3-III.A) can serve as a model for planning in other healthcare settings, including nursing homes and other residential care facilities, and primary care health centers. All healthcare facilities should do the following:

- Create a planning team and develop a written plan.
- Establish a decision-making and coordinating structure that can be tested during the Interpandemic Period and will be activated during an influenza pandemic.
- Determine how to conduct surveillance for pandemic influenza in healthcare personnel and, for residential facilities, in the population served.
- Develop policies and procedures for managing pandemic influenza in patients and staff.
- Educate and train healthcare personnel on pandemic influenza and the healthcare facility's response plan.
- Determine how the facility will communicate and coordinate with healthcare partners and public health authorities during a pandemic.
- Determine how the facility will communicate with patients and help educate the public regarding prevention and control measures.
- Develop a plan for procuring the supplies (e.g., personal protective equipment [PPE]) needed to manage influenza patients.
- Determine how the facility will participate in the community plan for distributing either vaccine or antiviral drugs, including possibly serving as a point of distribution and providing staff for alternative community points of distribution.

Emergency medical services, private homecare services, FQHCs, and rural health clinics may adapt their planning activities from this model. In some parts of the country, FQHCs and rural health clinics may need to rely on volunteers<sup>7</sup> to provide and administer pandemic influenza vaccines.

## 2. Alternative care sites

If an influenza pandemic causes severe illness in large numbers of people, hospital capacity might be overwhelmed. In that

<sup>7</sup> As mentioned in footnote #6, the HRSA Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) is helping each state and territory establish a standardized volunteer registration system. Additional information is available at: [www.hrsa.gov/bioterrorism/esarvhp/](http://www.hrsa.gov/bioterrorism/esarvhp/).

case, communities will need to provide care in alternative sites (e.g., school gymnasiums, armories, convention centers). (Also see <http://www.ahrq.gov/research/altsites.htm>.) The selection of alternative care sites for pandemic influenza should specifically address the following infection control and patient care needs:

- Bed capacity and spatial separation of patients
- Facilities and supplies for hand hygiene
- Lavatory and shower capacity for large numbers of patients
- Food services (refrigeration, food handling, and preparation)
- Medical services
- Staffing for patient care and support services
- PPE supplies
- Cleaning/disinfection supplies
- Environmental services (linen, laundry, waste)
- Safety and Security

## **S3-IV. RECOMMENDATIONS FOR THE PANDEMIC PERIOD**

### **A. Activating the facility's pandemic influenza response plan**

Following initial detection of pandemic influenza anywhere in the world, the facility's pandemic influenza response plan should be activated in accordance with the level of pandemic activity (see Table).

#### **1. Pandemic influenza reported outside the United States**

If cases of pandemic influenza have been reported outside the United States, the main steps will be to:

- Establish contact with key public health, healthcare, and community partners.
- Implement hospital surveillance for pandemic influenza, including detection of patients admitted for other reasons who might be infected with the pandemic strain of influenza virus.
- Implement a system for early detection and antiviral treatment of healthcare workers who might be infected with the pandemic strain of influenza virus.
- Reinforce infection control measures to prevent the spread of influenza (see S5-IV.B and Supplement 4).
- Accelerate the training of staff, in accordance with the facility's pandemic influenza education and training plan.

#### **2. Pandemic influenza reported in the United States**

If cases of pandemic influenza have been reported in the United States, additional steps will be to:

- Identify when pandemic influenza cases begin in the community. See also Supplement 1.
- Identify, isolate, and treat all patients with potential pandemic influenza. See also Supplements 4, 5, and 8.
- Implement activities to increase capacity, supplement staff shortages, and provide supplies and equipment.
- Maintain close communication within and among healthcare facilities and with state and local health departments.



## BOX 1. HEALTHCARE FACILITY PANDEMIC INFLUENZA PLANNING COMMITTEE

Representatives for a hospital pandemic influenza planning committee may include:

- **Hospital staff**
  - Administration/senior management (including fiscal officer)
  - Legal counsel/risk management
  - Infection control/hospital epidemiology
  - Hospital disaster/emergency coordinator
  - Engineering/physical plant/industrial hygiene/institutional safety
  - Nursing administration
  - Medical staff (including outpatient areas)
  - Intensive-care unit
  - Emergency department
  - Laboratory services
  - Respiratory therapy
  - Nutrition and food services
  - Pharmacy
  - Environmental services (housekeeping, laundry)
  - Public relations
  - Security
  - Materials management
  - Education/training/staff development
  - Occupational health
  - Diagnostic imaging
  - Information technology
- **Adjunct staff members**
  - Infectious diseases
  - Mental health (psychiatry, psychology)
  - Union representatives
  - Human resources
  - Social work
  - Director of house staff/fellowship and other training programs
  - Critical care medicine
  - Pathology
- **State and local health departments**
  - Communicable disease division
  - Laboratory services
  - Medical examiners
- **Community partners**
  - Emergency medical technicians ("first responders")
  - Local law enforcement
  - Funeral service personnel
  - Community service agencies
  - Federally qualified health centers (FQHC)\* and other healthcare safety net providers\*\*

\*A federally qualified health center (FQHC) is a type of provider defined by the Medicare and Medicaid statutes. FQHCs include health centers receiving grants under section 330 of the Public Health Service Act, certain tribal organizations, and clinics designated by HHS as FQHC Look-Alikes. More information may be found at: <http://www.cms.hhs.gov/providers/fqhc/>

\*\*Health care safety net providers deliver care to low income and other vulnerable populations, including the uninsured and those covered by Medicaid. Many of these providers have either a legal mandate or an explicit policy to provide services regardless of a patient's ability to pay (<http://www.ahcpr.gov/data/safetynet/faq.htm>). Major safety net providers include public hospitals and community health centers as well as teaching and community hospitals, and private physicians.

**BOX 2. EXAMPLES OF CONSUMABLE AND DURABLE SUPPLY NEEDS**

- **Consumable resources**
  - Hand hygiene supplies (antimicrobial soap and alcohol-based, waterless hand hygiene products)
  - Disposable N95, surgical and procedure masks
  - Face shields (disposable or reusable)
  - Gowns
  - Gloves
  - Facial tissues
  - Central line kits
  - Morgue packs
- **Durable resources:**
  - Ventilators
  - Respiratory care equipment
  - Beds
  - IV pumps

**TABLE 1. HOSPITAL PANDEMIC INFLUENZA TRIGGERS**

| Pandemic Influenza Level                                                                                                | Suggested Actions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Interpandemic Period</b>                                                                                             | <ul style="list-style-type: none"> <li>• Conduct planning</li> <li>• Conduct education/training</li> <li>• Conduct hospital surveillance for influenza (Supplement 1)</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Pandemic Alert Period</b>                                                                                            | <ul style="list-style-type: none"> <li>• Increase preparation; refine local plan</li> <li>• Conduct hospital surveillance for influenza (Supplement 1)</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Pandemic Period</b> <ul style="list-style-type: none"> <li>• Pandemic influenza outside the United States</li> </ul> | <ul style="list-style-type: none"> <li>• Establish contact with key public health, healthcare, and community partners.</li> <li>• Implement hospital surveillance for pandemic influenza (Supplement 1) in incoming patients and previously admitted patients.</li> <li>• Implement a system for early detection and treatment of healthcare personnel who might be infected with the pandemic strain of influenza.</li> <li>• Reinforce infection control procedures to prevent the spread of influenza (Supplement 4).</li> <li>• Accelerate staff training in accordance with the facility's pandemic influenza education and training plan.</li> </ul> |
| <ul style="list-style-type: none"> <li>• Pandemic influenza in the United States</li> </ul>                             | <p>As above, plus:</p> <ul style="list-style-type: none"> <li>• Implement activities to increase capacity, supplement staff, and provide supplies and equipment.</li> <li>• Maintain close contact with and among healthcare facilities and with state and local health departments.</li> <li>• Post signs for respiratory hygiene/cough etiquette.</li> <li>• Maintain high index of suspicion that patients presenting with influenza-like illness could be infected with pandemic strain.</li> </ul> <p>If pandemic strain is detected in local patient, community transmission can be assumed and hospital would move to next level of response.</p>   |

**TABLE 1. HOSPITAL PANDEMIC INFLUENZA TRIGGERS (cont.)**

| Pandemic Influenza Level                                                                                              | Suggested Actions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-----------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Pandemic Period (cont.)</b> <ul style="list-style-type: none"> <li>Pandemic influenza in the local area</li> </ul> | <p>As above, plus;</p> <ul style="list-style-type: none"> <li>Emergency department (ED) <ul style="list-style-type: none"> <li>Establish segregated waiting areas for persons with symptoms of influenza.</li> <li>Implement phone triage to discourage unnecessary ED/outpatient department visits.</li> <li>Enforce respiratory hygiene/cough etiquette.</li> </ul> </li> <li>Access controls <ul style="list-style-type: none"> <li>Limit number of visitors to those essential for patient support.</li> <li>Screen all visitors at point of entry to facility for signs and symptoms of influenza.</li> <li>Limit points of entry to facility; assign clinical staff to entry screening.</li> </ul> </li> <li>Hospital admissions <ul style="list-style-type: none"> <li>Defer elective admissions and procedures until local epidemic wanes.</li> <li>Discharge patients as soon as possible.</li> <li>Cohort patients admitted with influenza.</li> <li>Monitor for nosocomial transmission.</li> </ul> </li> <li>Staffing practices <ul style="list-style-type: none"> <li>Consider furlough or reassignment of pregnant staff and other staff at high risk for complications of influenza.</li> <li>Consider re-assigning non-essential staff to support critical hospital services or placing them on administrative leave; cohort staff caring for influenza patients.</li> <li>Consider assigning staff recovering from influenza to care for influenza patients.</li> <li>Implement system for detecting and reporting signs and symptoms of influenza in staff reporting for duty.</li> <li>Provide staff with antiviral prophylaxis, according to HHS recommendations (See Supplement 7).</li> </ul> </li> </ul> |

**TABLE 1. HOSPITAL PANDEMIC INFLUENZA TRIGGERS (cont.)**

| Pandemic Influenza Level                                                                                                                  | Suggested Actions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Pandemic Period (cont.)</b> <ul style="list-style-type: none"> <li>Nosocomial transmission</li> </ul>                                  | <p>As above, plus, if nosocomial transmission is limited to only a small number of units in the facility,</p> <ul style="list-style-type: none"> <li>Close units where there has been nosocomial transmission. <ul style="list-style-type: none"> <li>Cohort staff and patients.</li> <li>Restrict new admissions (except for other pandemic influenza patients) to affected units.</li> <li>Restrict visitors to the affected units to those who are essential for patient care and support.</li> </ul> </li> </ul> <p>See also <b>Supplement 4</b>.</p>                 |
| <ul style="list-style-type: none"> <li>Widespread transmission in community and hospital; patient admissions at surge capacity</li> </ul> | <p>As above plus:</p> <ul style="list-style-type: none"> <li>Redirect personnel resources to support patient care (e.g., administrative clinical staff, clinical staff working in departments that have been closed [e.g., physical/occupational therapy, cardiac catheterization]).</li> <li>Recruit community volunteers (e.g., retired nurses and physicians, clinical staff working in outpatient settings).</li> <li>Consider placing on administrative leave all non-essential personnel who cannot be reassigned to support critical hospital services.</li> </ul> |

## APPENDIX 1. RESOURCES LIST FOR HEALTHCARE PLANNING

### PANDEMIC INFLUENZA PLANS

**Currently available State Plans** may be found on the following Council of State and Territorial Epidemiologists website:  
<http://www.cste.org/specialprojects/Influenzaplans/StateMap.asp>.

**Currently available National Plans** may be found on the following WHO website:  
<http://www.who.int/csr/disease/influenza/nationalpandemic/en/index.html>

#### WHO Global Influenza Preparedness Plan

([http://www.who.int/csr/resources/publications/influenza/WHO\\_CDS\\_CSR\\_GIP\\_2005\\_5/en/index.html](http://www.who.int/csr/resources/publications/influenza/WHO_CDS_CSR_GIP_2005_5/en/index.html) )

Document defines the role of WHO and recommendations for national measures before and during pandemics.

#### WHO Checklist for Influenza Pandemic Preparedness Planning

([http://www.who.int/csr/resources/publications/influenza/WHO\\_CDS\\_CSR\\_GIP\\_2005\\_4/en/index.html](http://www.who.int/csr/resources/publications/influenza/WHO_CDS_CSR_GIP_2005_4/en/index.html) )

### Tools

#### FluAid

(<http://www2.cdc.gov/od/fluid/default.htm>)

FluAid 2.0 provides estimates of the total deaths, hospitalizations, and outpatient visits that might occur during an influenza pandemic.

#### FluSurge

(<http://www.cdc.gov/flu/flusurge.htm>)

This specialized spreadsheet-based software estimates the potential surge in demand for hospital-based health care during a pandemic. For each week of a pandemic, FluSurge calculates the potential demand for hospital beds, intensive care unit beds, and mechanical ventilators. Demand for resources is compared with actual capacity. FluSurge is a companion to the previously released FluAid 2.0.

#### AHRQ's Health Emergency Assistance Line and Triage Hub (HEALTH) Mode

The model is designed to minimize surges in patient demand on the health care delivery system during a bioterrorist event or other public health emergency.

1. Full Report—Health Emergency Assistance Line and Triage Hub (HEALTH) Model (AHRQ Publication No. 05-0040)  
 (<http://www.ahrq.gov/research/health/health.pdf> )  
 This report helps planners determine the requirements, specifications, and resources needed for developing an emergency contact center such as the HEALTH model.
2. Contact Center Assessment Tool Set  
 (<http://www.ahrq.gov/research/health/health.asp>)

#### AHRQ Bioterrorism Planning and Response Resource Page

<http://www.ahrq.gov/browse/bioterbr.htm>

This resource includes a listing of a variety of tools and resources on issues from community prophylaxis to surge capacity in health facilities.

#### Emergency Preparedness Resource Inventory (EPRI): A Tool for Local, Regional, and State Planners

(<http://www.ahrq.gov/research/epri/> )

The Emergency Preparedness Resource Inventory (EPRI) is a tool allowing local or regional planners to assemble an inventory of critical resources that would be useful in responding to a bioterrorist attack. In addition to a Web-based software tool, EPRI includes an Implementation Report, a Technical Manual, and an Appendix.

**Altered Standards of Care in Mass Casualty Events**

(<http://www.ahrq.gov/research/altstand/index.html> )

This report discusses the potential of a mass casualty event to compromise the ability of health systems to deliver services meeting established standards of care.

**Computer Staffing Model for Bioterrorism Response**

(<http://www.ahrq.gov/research/biomodel.htm> )

This new resource is the Nation's first computerized staffing model that is downloadable as a spreadsheet or accessible as a Web-based version. It can be used to calculate the specific needs of local health care systems based on the number of staff they have and the number of patients they would need to treat quickly in a bioterrorism event.

**Rocky Mountain Regional Care Model for Bioterrorist Events: Locate Alternate Care Sites During an Emergency**

(<http://www.ahrq.gov/research/altsites.htm> )

The alternate care site selection tool is designed to allow regional planners to locate and rank potential alternative sites—stadiums, schools, recreation centers, motels, and other venues—based on whether they have adequate ventilation, plumbing, food supply and kitchen facilities, and other factors.

**HRSA Bioterrorism and Hospital Preparedness**

(<http://www.hrsa.gov/bioterrorism/preparationandplanning/healthcare&facilities.htm>)

A comprehensive list of resources and documents

**ASTHO "Preparedness Planning for State Health Officials – Nature's Terrorist Attack – Pandemic Influenza"**

(<http://www.astho.org/pubs/PandemicInfluenza.pdf> )

Provides checklists for state health officials to assist in preparedness planning. A brief summary of major issues to consider is also included.

**Educational Materials samples**

(<http://www.health.state.ny.us/nysdoh/flu/resources.htm> )

**HHS healthcare surge capacity document**

([http://www.os.hhs.gov/asphelp/mscc\\_handbook.html](http://www.os.hhs.gov/asphelp/mscc_handbook.html) )

**OSHA—Best Practices for the Protection of Hospital-Based First Receivers**

([http://www.osha.gov/dts/osta/bestpractices/html/hospital\\_firstreceivers.html](http://www.osha.gov/dts/osta/bestpractices/html/hospital_firstreceivers.html))

**ASTM Standard Guide for Hospital Preparedness and Response**

The purpose of the guide is to answer questions regarding the minimal levels of preparedness needed for hospitals to deal with a large-scale terrorist attack or other serious emergency and includes guidelines regarding the process for preparedness and mitigation; the process of organizing and planning a hospital response plan; the nature of supplies that hospitals need to make available; the application of existing regulations and guidelines; and an acceptable means to protect the facilities for usual operation, patients, and staff while continuing to provide an effective level of response. (This document is not free to the public, a document summary is available at [http://www.astm.org/cgi-bin/SoftCart.exe/DATABASE.CART/REDLINE\\_PAGES/E2413.htm?L+mystore+vybd9920](http://www.astm.org/cgi-bin/SoftCart.exe/DATABASE.CART/REDLINE_PAGES/E2413.htm?L+mystore+vybd9920))

**Information on Handling Human Remains During Mass-Casualty Events**

- Interim Health Recommendations for Workers who Handle Human Remains  
[www.bt.cdc.gov/disasters/tsunamis/handleremains.asp](http://www.bt.cdc.gov/disasters/tsunamis/handleremains.asp)
- Disposing of Liquid Waste from Autopsies in Tsunami-Affected Areas  
[www.bt.cdc.gov/disasters/tsunamis/pdf/tsunami-autopsyliquidwaste.pdf](http://www.bt.cdc.gov/disasters/tsunamis/pdf/tsunami-autopsyliquidwaste.pdf)



- Management of Dead Bodies in Disaster Situations  
[www.paho.org/English/DD/PED/ManejoCadaveres.htm](http://www.paho.org/English/DD/PED/ManejoCadaveres.htm)
- Health Concerns Associated with Disaster Victim Identification After a Tsunami—Thailand, Dec 26, 2004–Mar 31, 2005 . MMWR 15 April 2005;54(14):349–52. [www.cdc.gov/mmwr/preview/mmwrhtml/mm5414a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5414a1.htm)

## Presentations

### 2004 AHRQ-sponsored series "Addressing Surge Capacity in a Mass Casualty Event"

(<http://www.hsrnet.net/ahrq/surgecapacity/> )

### Presentations from First National Congress on Public Health Readiness

(<http://www.ama-assn.org/ama/noindex/category/11053.html> )

(<http://www.bt.cdc.gov/training/ncphr/> ) -CDC Presentations only

These slideshows represent presentations from speakers at the 1st National Congress on Public Health Readiness held July 20–22, 2004.

### "No Vacancy: Healthcare Surge Capacity in Disasters."

(<http://www.ama-assn.org/ama1/pub/upload/mm/415/hick.ppt> )

Jonathan L. Hick, MD, Medical Director, Office of Emergency Preparedness, Hennepin County Medical Center, Minneapolis, Minnesota

### Bioterrorism Preparedness: A Hospital Tabletop Exercise

SHEA 14th Annual Scientific Meeting, Philadelphia, PA

April 17, 2004

Prepared by Kelly Henning, MD

## APPENDIX 2. HOSPITAL PREPAREDNESS CHECKLIST

| Preparedness Subject                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Actions Needed |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| 1. Structure for planning and decision making                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                |
| <input type="checkbox"/> An internal, multidisciplinary planning committee for influenza preparedness has been created.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                |
| <input type="checkbox"/> A person has been designated as the influenza preparedness coordinator.<br>(Insert name) _____                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                |
| <input type="checkbox"/> Members of the planning committee include the following hospital staff members (insert names) <div> <input type="checkbox"/> Administration _____<br/> <input type="checkbox"/> Legal counsel _____<br/> <input type="checkbox"/> Infection control _____<br/> <input type="checkbox"/> Hospital disaster coordinator _____<br/> <input type="checkbox"/> Risk management _____<br/> <input type="checkbox"/> Facility engineering _____<br/> <input type="checkbox"/> Nursing administration _____<br/> <input type="checkbox"/> Medical staff _____<br/> <input type="checkbox"/> Intensive care _____<br/> <input type="checkbox"/> Emergency Department _____<br/> <input type="checkbox"/> Laboratory services _____<br/> <input type="checkbox"/> Respiratory therapy _____<br/> <input type="checkbox"/> Psychiatry _____<br/> <input type="checkbox"/> Environmental services _____<br/> <input type="checkbox"/> Public relations _____<br/> <input type="checkbox"/> Security _____<br/> <input type="checkbox"/> Materials management _____<br/> <input type="checkbox"/> Staff development _____<br/> <input type="checkbox"/> Occupational health _____<br/> <input type="checkbox"/> Diagnostic imaging _____<br/> <input type="checkbox"/> Pharmacy _____<br/> <input type="checkbox"/> Information technology _____<br/> <input type="checkbox"/> Other members _____<br/> <input type="checkbox"/> Other members _____ </div> |                |

| Preparedness Subject                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Actions Needed |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| <input type="checkbox"/> A state or local health department person has been identified as a committee liaison.<br>(Insert name) _____                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                |
| <input type="checkbox"/> A linkage with local or regional emergency preparedness groups has been established<br>(Planning organization) _____                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                |
| 2. Development of a written pandemic influenza plan                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                |
| <input type="checkbox"/> A written plan has been completed or is in progress that includes the elements listed in #3 below.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                |
| <input type="checkbox"/> The plan specifies the circumstances under which the plan will be activated.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                |
| <input type="checkbox"/> The plan describes the organization structure that will be used to operationalize the plan.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                |
| <input type="checkbox"/> Responsibilities of key personnel related to executing the plan have been described.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                |
| <input type="checkbox"/> A simulation exercise has been developed to test the effectiveness of the plan.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                |
| <input type="checkbox"/> A simulation exercise has been performed. (Date performed _____)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                |
| 3. Elements of an influenza pandemic plan                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                |
| <input type="checkbox"/> A surveillance plan has been developed. <input type="checkbox"/> Syndromic surveillance has been established in the emergency room. <input type="checkbox"/> Criteria for distinguishing pandemic influenza is part of the syndromic surveillance plan. <input type="checkbox"/> Responsibility has been assigned for reviewing global, national, regional, and local influenza activity trends and informing the pandemic influenza coordinator of evidence of an emerging problem. (Name _____) <input type="checkbox"/> Thresholds for heightened local surveillance for pandemic influenza have been established. <input type="checkbox"/> A system has been created for internal review of pandemic influenza activity in patients presenting to the emergency department. <input type="checkbox"/> A system for monitoring for nosocomial transmission of pandemic has been implemented and tested by monitoring for non-pandemic influenza. |                |

## Actions Needed

## Preparedness Subject

- ☐ A communication plan has been developed.
- ☐ Responsibility for external communication has been assigned.  
 Person responsible for updating public health reporting \_\_\_\_\_  
 Clinical spokesperson for the facility \_\_\_\_\_  
 Media spokesperson for the facility \_\_\_\_\_
- ☐ Key points of contact outside the facility have been identified.  
 State health department contact \_\_\_\_\_  
 Local health department contact \_\_\_\_\_  
 Newspaper contact(s) \_\_\_\_\_  
 Radio contact(s) \_\_\_\_\_  
 Public official(s) \_\_\_\_\_
- ☐ A list of other healthcare facilities with whom it will be necessary to maintain communication has been established.
- ☐ A meeting with local healthcare facilities has been held to discuss a communication strategy.
- ☐ A plan for updating key facility personnel on a daily basis has been established.
- The person(s) responsible for providing these updates are: \_\_\_\_\_
- ☐ A system to track pandemic influenza admissions and discharges has been developed and tested by monitoring non-pandemic influenza admissions and discharges in the community.
- ☐ A strategy for regularly updating clinical, ED, and outpatient staff on the status of pandemic influenza, once detected, has been established. (Responsible person \_\_\_\_\_)
- ☐ A plan for informing patients and visitors about the level of pandemic influenza activity has been established.
- ☐ An education and training plan on pandemic influenza has been developed.
- ☐ Language and reading level-appropriate materials for educating all personnel about pandemic influenza and the facility's pandemic influenza plan, have been identified.
- ☐ Current and potential sites for long-distance and local education of clinicians on pandemic influenza have been identified.
- ☐ Means for accessing state and federal web-based influenza training programs have been identified.
- ☐ A system for tracking which personnel have completed pandemic influenza training is in place.
- ☐ A plan is in place for rapidly training non-facility staff brought in to provide patient care when the hospital reaches surge capacity. \_\_\_\_\_

| Preparedness Subject                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Actions Needed |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| <input type="checkbox"/> The following groups of healthcare personnel have received training on the facility's influenza plan: <ul style="list-style-type: none"> <li><input type="checkbox"/> Attending physicians</li> <li><input type="checkbox"/> House staff</li> <li><input type="checkbox"/> Nursing staff</li> <li><input type="checkbox"/> Laboratory staff</li> <li><input type="checkbox"/> Emergency Department personnel</li> <li><input type="checkbox"/> Outpatient personnel</li> <li><input type="checkbox"/> Environmental Services personnel</li> <li><input type="checkbox"/> Engineering and maintenance personnel</li> <li><input type="checkbox"/> Security personnel</li> <li><input type="checkbox"/> Nutrition personnel</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                |
| <input type="checkbox"/> A <b>triage and admission plan</b> has been developed. <ul style="list-style-type: none"> <li><input type="checkbox"/> A specific location has been identified for triage of patients with possible pandemic influenza.</li> <li><input type="checkbox"/> The plan includes use of signage to direct and instruct patients with possible pandemic influenza on the triage process.</li> <li><input type="checkbox"/> Patients with possible pandemic influenza will be physically separated from other patients seeking medical attention.</li> <li><input type="checkbox"/> A system for phone triage of patients for purposes of prioritizing patients who require a medical evaluation has been developed. <ul style="list-style-type: none"> <li><input type="checkbox"/> Criteria for determining which patients need a medical evaluation are in place.</li> </ul> </li> <li><input type="checkbox"/> A method for tracking the admission and discharge of patients with pandemic influenza has been developed. <ul style="list-style-type: none"> <li><input type="checkbox"/> The tracking method has been tested with non-pandemic influenza patients. _____</li> </ul> </li> </ul> |                |
| <input type="checkbox"/> A <b>facility access plan</b> has been developed. <ul style="list-style-type: none"> <li><input type="checkbox"/> Criteria and protocols for closing the facility to new admissions are in place.</li> <li><input type="checkbox"/> Criteria and protocols for limiting visitors have been established.</li> <li><input type="checkbox"/> Hospital Security has had input into procedures for enforcing facility access controls. _____</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                |
| <input type="checkbox"/> An <b>occupational health plan</b> has been developed. <ul style="list-style-type: none"> <li><input type="checkbox"/> A system for rapidly delivering vaccine or antiviral prophylaxis to healthcare personnel has been developed. <ul style="list-style-type: none"> <li><input type="checkbox"/> The system has been tested during a non-pandemic influenza season.</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                |

| Preparedness Subject                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Actions Needed |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| <ul style="list-style-type: none"> <li><input type="checkbox"/> A method for prioritizing healthcare personnel for receipt of vaccine or antiviral prophylaxis based on level of patient contact and personal risk for influenza complications has been established.</li> <li><input type="checkbox"/> A system for detecting symptomatic personnel before they report for duty has been developed.               <ul style="list-style-type: none"> <li><input type="checkbox"/> This system has been tested during a non-pandemic influenza period.</li> </ul> </li> <li><input type="checkbox"/> A policy for managing healthcare personnel with symptoms of or documented pandemic influenza has been established. The policy considers:               <ul style="list-style-type: none"> <li><input type="checkbox"/> When personnel may return to work after having pandemic influenza</li> <li><input type="checkbox"/> When personnel who are symptomatic but well enough to work, will be permitted to continue working</li> </ul> </li> <li><input type="checkbox"/> A method for furloughing or altering the work locations of personnel who are at high risk for influenza complications (e.g., pregnant women, immunocompromised healthcare workers) has been developed.</li> <li><input type="checkbox"/> Mental health and faith-based resources who will provide counseling to personnel during a pandemic have been identified.</li> <li><input type="checkbox"/> A strategy for housing healthcare personnel who may be needed on-site for prolonged periods of time is in place.</li> <li><input type="checkbox"/> A strategy for accommodating and supporting personnel who have child or elder care responsibilities has been developed. _____</li> </ul> |                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                |
| <ul style="list-style-type: none"> <li><input type="checkbox"/> A vaccine and antiviral use plan has been developed.</li> <li><input type="checkbox"/> A contact for obtaining influenza vaccine has been identified.               <ul style="list-style-type: none"> <li>(Name) _____</li> </ul> </li> <li><input type="checkbox"/> A contact for obtaining antiviral prophylaxis has been identified.               <ul style="list-style-type: none"> <li>(Name) _____</li> </ul> </li> <li><input type="checkbox"/> A priority list (based on HHS guidance for use of vaccines and antivirals in a pandemic when in short supply) and estimated number of patients and healthcare personnel who would be targeted for influenza vaccination or antiviral prophylaxis has been developed.               <ul style="list-style-type: none"> <li><input type="checkbox"/> Number of first priority personnel _____</li> <li><input type="checkbox"/> Number of second priority personnel _____</li> <li><input type="checkbox"/> Number of remaining personnel _____</li> <li><input type="checkbox"/> Number of first priority patients _____</li> <li><input type="checkbox"/> Number of second priority patients _____</li> </ul> </li> <li><input type="checkbox"/> A system for rapidly distributing vaccine and antivirals to patients has been developed.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                  |                |

## Preparedness Subject

## Actions Needed

- ☐ Issues related to **surge capacity** have been addressed.
- ☐ A plan is in place to address **unmet staffing needs** in the hospital.
  - ☐ The minimum number and categories of personnel needed to care for a group of patients with pandemic influenza has been determined.
  - ☐ Responsibility for assessing day-to-day clinical staffing needs during an influenza pandemic has been assigned.
- Persons responsible are: (names and/or titles) \_\_\_\_\_
- ☐ Legal counsel has reviewed emergency laws for using healthcare personnel with out-of-state licenses.
- ☐ Legal counsel has made sure that any insurance and other liability concerns have been resolved.
- ☐ Criteria for declaring a "staffing crisis" that would enable the use of emergency staffing alternatives have been defined.
- ☐ The plan includes linking to local and regional planning and response groups to collaborate on addressing widespread healthcare staffing shortages during a crisis.
- ☐ A priority list for reassignment and recruitment of personnel has been developed.
- ☐ A method for rapidly credentialing newly recruited personnel has been developed.
- ☐ Mutual AID Agreements (MAAs) and Memoranda of Understanding/Agreement (MOU/As) have been signed with other facilities that have agreed to share their staff, as needed.
- ☐ Strategies to **increase bed capacity** have been identified
  - ☐ A threshold has been established for canceling elective admissions and surgeries
  - ☐ MOAs have been signed with facilities that would accept non-influenza patients in order to free-up bed space
  - ☐ Areas of the facility that could be utilized for expanded bed space have been identified
  - ☐ The estimated patient capacity for this facility is \_\_\_\_\_
  - ☐ Plans for expanded bed capacity have been discussed with local and regional planning groups
- ☐ Anticipated **durable and consumable resource** needs have been determined
  - ☐ A primary plan and contingency plan to address supply shortages has been developed
  - ☐ Plans for obtaining limited resources have been discussed with local and regional planning and response groups.



## Preparedness Subject

- ☐ A strategy for handling increased numbers of deceased persons has been developed.
- ☐ Plans for expanding morgue capacity have been discussed with local and regional planning groups.
- ☐ Local morticians have been involved in planning discussions.
- ☐ Mortality estimates have been used to estimate the number of body bags and shrouds.
- ☐ Supply sources for postmortem materials have been identified. \_\_\_\_\_

## Actions Needed



# supplement 4 infection control

## TABLE OF CONTENTS

|                                                                                                                   |             |
|-------------------------------------------------------------------------------------------------------------------|-------------|
| <b>S4-I. RATIONALE .....</b>                                                                                      | <b>S4-3</b> |
| <b>S4-II. INFLUENZA TRANSMISSION .....</b>                                                                        | <b>S4-3</b> |
| A. Modes of transmission.....                                                                                     | S4-3        |
| 1. Droplet transmission.....                                                                                      | S4-3        |
| 2. Contact transmission.....                                                                                      | S4-4        |
| 3. Airborne transmission .....                                                                                    | S4-4        |
| B. Pathogenesis of influenza and implications for infection control .....                                         | S4-5        |
| C. Control of transmission in healthcare settings.....                                                            | S4-5        |
| <b>S4-III. OVERVIEW .....</b>                                                                                     | <b>S4-5</b> |
| <b>S4-IV. RECOMMENDATIONS FOR INFECTION CONTROL IN HEALTHCARE SETTINGS .....</b>                                  | <b>S4-6</b> |
| A. Basic infection control principles for preventing the spread of pandemic influenza in healthcare settings..... | S4-6        |
| B. Management of infectious patients .....                                                                        | S4-7        |
| 1. Respiratory hygiene/cough etiquette .....                                                                      | S4-7        |
| 2. Droplet precautions and patient placement .....                                                                | S4-7        |
| C. Infection control practices for healthcare personnel.....                                                      | S4-7        |
| 1. Personal protective equipment (PPE).....                                                                       | S4-8        |
| a) PPE for standard and droplet precautions .....                                                                 | S4-8        |
| b) PPE for special circumstances .....                                                                            | S4-9        |
| c) Caring for patients with pandemic influenza .....                                                              | S4-9        |
| 2. Hand hygiene.....                                                                                              | S4-9        |
| 3. Disposal of solid waste.....                                                                                   | S4-10       |
| 4. Linen and laundry .....                                                                                        | S4-10       |
| 5. Dishes and eating utensils.....                                                                                | S4-10       |
| 6. Patient-care equipment.....                                                                                    | S4-10       |
| 7. Environmental cleaning and disinfection.....                                                                   | S4-11       |
| a) Cleaning and disinfection of patient-occupied rooms.....                                                       | S4-11       |
| b) Cleaning and disinfection after patient discharge or transfer .....                                            | S4-11       |
| 8. Postmortem care .....                                                                                          | S4-11       |
| 9. Laboratory specimens and practices.....                                                                        | S4-11       |
| D. Occupational health issues.....                                                                                | S4-11       |
| E. Reducing exposure of persons at risk for complications of pandemic influenza.....                              | S4-12       |
| F. Healthcare setting-specific guidance .....                                                                     | S4-12       |
| 1. Hospitals .....                                                                                                | S4-12       |
| a) Detection of persons entering the facility who may have pandemic influenza .....                               | S4-12       |
| b) "Source control" measures to limit dissemination of influenza virus from respiratory secretions.....           | S4-13       |

|                                                                                                           |              |
|-----------------------------------------------------------------------------------------------------------|--------------|
| c) Hospitalization of pandemic influenza patients.....                                                    | S4-13        |
| d) Control of nosocomial pandemic influenza transmission.....                                             | S4-14        |
| 2. Nursing homes and other residential facilities.....                                                    | S4-14        |
| a) Prevention or delay of pandemic influenza virus entry into the facility .....                          | S4-15        |
| b) Monitoring patients for pandemic influenza and instituting appropriate<br>control measures.....        | S4-15        |
| 3. Prehospital care (emergency medical services).....                                                     | S4-15        |
| 4. Home healthcare services.....                                                                          | S4-16        |
| 5. Outpatient medical offices.....                                                                        | S4-16        |
| a) Detection of patients with possible pandemic influenza .....                                           | S4-16        |
| b) "Source control" measures .....                                                                        | S4-16        |
| c) Patient placement.....                                                                                 | S4-17        |
| 6. Other ambulatory settings .....                                                                        | S4-17        |
| G. Care of pandemic influenza patients in the home.....                                                   | S4-17        |
| 1. Management of influenza patients.....                                                                  | S4-17        |
| 2. Management of other persons in the home.....                                                           | S4-18        |
| 3. Infection control measures in the home.....                                                            | S4-18        |
| H. Care of pandemic influenza patients at alternative sites .....                                         | S4-18        |
| <b>S4-V. RECOMMENDATIONS FOR INFECTION CONTROL IN SCHOOLS AND WORKPLACES....</b>                          | <b>S4-18</b> |
| <b>S4-VI. RECOMMENDATIONS FOR INFECTION CONTROL IN COMMUNITY SETTINGS .....</b>                           | <b>S4-19</b> |
| Box 1. Summary of Infection Control Recommendations for Care of Patients with<br>Pandemic Influenza ..... | S4-20        |
| Box 2. Respiratory Hygiene/Cough Etiquette.....                                                           | S4-22        |

## S4-I. RATIONALE

The primary strategies for preventing pandemic influenza are the same as those for seasonal influenza: vaccination, early detection and treatment with antiviral medications (as discussed elsewhere in this plan), and the use of infection control measures to prevent transmission during patient care. However, when a pandemic begins, a vaccine may not yet be widely available, and the supply of antiviral drugs may be limited. The ability to limit transmission in healthcare settings will, therefore, rely heavily on the appropriate and thorough application of infection control measures. While it is commonly accepted that influenza transmission requires close contact—via exposure to large droplets (droplet transmission), direct contact (contact transmission), or near-range exposure to aerosols (airborne transmission)—the relative clinical importance of each of these modes of transmission is not known.

The infection control guidance provided in this supplement is based on our knowledge of routes of influenza transmission (S4-II.A), the pathogenesis of influenza (S4-II.B), and the effects of influenza control measures used during past pandemics and interpandemic periods (S4-II.C) (see also supporting references in the Appendix). Given some uncertainty about the characteristics of a new pandemic strain, all aspects of preparedness planning for pandemic influenza must allow for flexibility and real-time decision-making that take new information into account as the situation unfolds. The specific characteristics of a new pandemic virus—virulence, transmissibility, initial geographic distribution, clinical manifestation, risk to different age groups and subpopulations, and drug susceptibility—will remain unknown until the pandemic gets underway. If the new virus is unusual in any of these respects, HHS and its partners will provide updated infection control guidance.

## S4-II. INFLUENZA TRANSMISSION

### A. Modes of transmission

Despite the prevalence of influenza year after year, most information on the modes of influenza transmission from person to person is indirect and largely obtained through observations during outbreaks in healthcare facilities and other settings (e.g., cruise ships, airplanes, schools, and colleges); the amount of direct scientific information is very limited. However, the epidemiologic pattern observed is generally consistent with spread through close contact (i.e., exposure to large respiratory droplets, direct contact, or near-range exposure to aerosols). While some observational and animal studies support airborne transmission through small particle aerosols, there is little evidence of airborne transmission over long distances or prolonged periods of time (as is seen with *M. tuberculosis*). The relative contributions and clinical importance of the different modes of influenza transmission are currently unknown.

#### 1. Droplet transmission ([www.cdc.gov/ncidod/hip/ISOLAT/std\\_prec\\_excerpt.htm](http://www.cdc.gov/ncidod/hip/ISOLAT/std_prec_excerpt.htm))

Droplet transmission involves contact of the conjunctivae or the mucous membranes of the nose or mouth of a susceptible person with large-particle droplets containing microorganisms generated from a person who has a clinical disease or who is a carrier of the microorganism. Droplets are generated from the source person primarily during coughing, sneezing, or talking and during the performance of certain procedures such as suctioning and bronchoscopy. Transmission via large-particle droplets requires close contact between source and recipient persons, because droplets do not remain suspended in the air and generally travel only short distances (about 3 feet) through the air. Because droplets do not remain suspended in the air, special air handling and ventilation are not required to prevent droplet transmission.

Based on epidemiologic patterns of disease transmission, large droplet transmission has been considered a major route of influenza transmission. However, data directly demonstrating large droplet transmission of influenza in human outbreaks is indirect and limited.

## 2. Contact transmission ([www.cdc.gov/ncidod/hip/ISOLAT/contact\\_prec\\_excerpt.htm](http://www.cdc.gov/ncidod/hip/ISOLAT/contact_prec_excerpt.htm))

Direct-contact transmission involves skin-to-skin contact and physical transfer of microorganisms to a susceptible host from an infected or colonized person, such as occurs when personnel turn patients, bathe patients, or perform other patient-care activities that require physical contact. Direct-contact transmission also can occur between two patients (e.g., by hand contact), with one serving as the source of infectious microorganisms and the other as a susceptible host. Indirect-contact transmission involves contact of a susceptible host with a contaminated intermediate object, usually inanimate, in the patient's environment.

Contact transmission of influenza may occur through either direct skin-to-skin contact or through indirect contact with virus in the environment. Transmission via contaminated hands and fomites has been suggested as a contributing factor in some studies. However, there is insufficient data to determine the proportion of influenza transmission that is attributable to direct or indirect contact.

## 3. Airborne transmission ([www.cdc.gov/ncidod/hip/ISOLAT/airborne\\_prec\\_excerpt.htm](http://www.cdc.gov/ncidod/hip/ISOLAT/airborne_prec_excerpt.htm))

Airborne transmission occurs by dissemination of either airborne droplet nuclei or small particles in the respirable size range containing the infectious agent. Microorganisms carried in this manner—such as *M. tuberculosis*—may be dispersed over long distances by air currents and may be inhaled by susceptible individuals who have not had face-to-face contact with (or been in the same room with) the infectious individual. Organisms transmitted in this manner must be capable of sustaining infectivity, despite desiccation and environmental variation that generally limit survival in the airborne state. Preventing the spread of agents that are transmitted by the airborne route requires the use of special air handling and ventilation systems (e.g., negative pressure rooms).

The relative contribution of airborne transmission to influenza outbreaks is uncertain. Evidence is limited and is principally derived from laboratory studies in animals and some observational studies of influenza outbreaks in humans, particularly on cruise ships and airplanes, where other mechanisms of transmission were also present. Additional information suggesting airborne transmission was reported in a Veterans Administration Hospital study that found lower rates of influenza in wards exposed to ultraviolet radiation (which inactivates influenza viruses) than in wards without UV radiation. Another study indicated that humidity can play a role in the infectivity of aerosolized influenza, although the influence of humidity on the formation of droplet nuclei was not evaluated.

**Small-particle aerosols.** There is no evidence that influenza transmission can occur across long distances (e.g., through ventilation systems) or through prolonged residence in air, as seen with airborne diseases such as tuberculosis. However, transmission may occur at shorter distances through inhalation of small-particle aerosols (droplet nuclei), particularly in shared air spaces with poor air circulation. An experimental study involving human volunteers found that illness could be induced with substantially lower virus titers when influenza virus was administered as a small droplet aerosol rather than as nasal droplets, suggesting that infection is most efficiently induced when virus is deposited in the lower rather than the upper respiratory tract. While this study supports the possibility of droplet nuclei transmission of influenza, the proportion of infections acquired through droplet nuclei—as compared with large droplet or contact spread—is unknown.

It is likely that some aerosol-generating procedures (e.g., endotracheal intubation, suctioning, nebulizer treatment, bronchoscopy) could increase the potential for dissemination of droplet nuclei in the immediate vicinity of the patient. (Although transmission of SARS-CoV was reported in a Canadian hospital during an aerosol-generating procedure [intubation], it occurred in a situation involving environmental contamination with respiratory secretions.) Although this mode of transmission has not been evaluated for influenza, additional precautions for healthcare personnel who perform aerosol-generating procedures on influenza patients may be warranted.

## B. Pathogenesis of influenza and implications for infection control

The cellular pathogenesis of human influenza indicates that infection principally takes place within the respiratory tract. While conjunctivitis is a common manifestation of systemic influenza infection, the ocular route of inoculation and infection has not been demonstrated for human influenza viruses. This may not be true with certain avian species of influenza (e.g., H7N7) that have been associated primarily with conjunctivitis in humans.<sup>1</sup> This information suggests that preventing direct and indirect inoculation of the respiratory tract is of utmost importance for preventing person-to-person transmission when caring for infectious patients.

## C. Control of transmission in healthcare facilities

Outbreaks of influenza have been prevented or controlled through a set of well established strategies that include vaccination of patients and healthcare personnel; early detection of influenza cases in a facility; use of antivirals to treat ill persons and, if recommended, as prophylaxis; isolation of infectious patients in private rooms or cohort units; use of appropriate barrier precautions during patient care, as recommended for Standard and Droplet Precautions (Box 1); and administrative measures, such as restricting visitors, educating patients and staff, and cohorting healthcare workers assigned to an outbreak unit.

These are the primary infection control measures recommended in this plan. They will be updated, as necessary, based on the observed characteristics of the pandemic influenza virus.

## S4-III. OVERVIEW

**Supplement 4** provides guidance to healthcare and public health partners on basic principles of infection control for limiting the spread of pandemic influenza. These principles (summarized in Box 1) are common to the prevention of other infectious agents spread by respiratory droplets. **Supplement 4** also includes guidance on the selection and use of personal protective equipment (PPE); hand hygiene and safe work practices; cleaning and disinfection of environmental surfaces; handling of laboratory specimens; and post-mortem care. The guidance also covers infection control practices related to the management of infectious patients, the protection of persons at high-risk for severe influenza or its complications, and issues concerning occupational health.

**Supplement 4** also provides guidance on how to adapt infection control practices in specific healthcare settings, including hospitals, nursing homes and other long-term care facilities, pre-hospital care (emergency medical services [EMS]), medical offices and other ambulatory care settings, and during the provision of professional home healthcare services. The section on hospital care covers detection of entering patients who may be infected with pandemic influenza; implementation of source-control measures to limit virus dissemination from respiratory secretions; hospitalization of pandemic influenza patients; and detection and control of nosocomial transmission.

In addition, **Supplement 4** includes guidance on infection control procedures for pandemic influenza patients in the home or in alternative care sites that may be established if local hospital capacity is overwhelmed by a pandemic. Finally, it includes recommendations on infection control in schools, workplaces, and community settings.

**Supplement 4** does not address the use of vaccines and antivirals in the control of influenza transmission in healthcare settings and the community. These issues are addressed in **Supplements 6 and 7**, respectively.

<sup>1</sup> Eye protection is recommended when working with conjunctivitis-inducing avian influenza viruses

## S4-IV. RECOMMENDATIONS FOR INFECTION CONTROL IN HEALTHCARE SETTINGS

The recommendations for infection control described below are generally applicable throughout the different pandemic phases. In some cases, as indicated, recommendations may be modified as the situation progresses from limited cases to widespread community illness.

### A. Basic infection control principles for preventing the spread of pandemic influenza in healthcare settings

The following infection control principles apply in any setting where persons with pandemic influenza might seek and receive healthcare services (e.g. hospitals, emergency departments, out-patient facilities, residential care facilities, homes). Details of how these principles may be applied in each healthcare setting follow.

- Limit contact between infected and non-infected persons<sup>2</sup>
  - Isolate infected persons (i.e., confine patients to a defined area as appropriate for the healthcare setting).
  - Limit contact between nonessential personnel and other persons (e.g., social visitors) and patients who are ill with pandemic influenza.
  - Promote spatial separation in common areas (i.e., sit or stand as far away as possible—at least 3 feet—from potentially infectious persons) to limit contact between symptomatic and non-symptomatic persons.
- Protect persons caring for influenza patients in healthcare settings from contact with the pandemic influenza virus. Persons who must be in contact should:
  - Wear a surgical or procedure mask<sup>3</sup> for close contact with infectious patients.
  - Use contact and airborne precautions, including the use of N95 respirators, when appropriate [S4-IV.C].
  - Wear gloves (gown if necessary) for contact with respiratory secretions.
  - Perform hand hygiene after contact with infectious patients.
- Contain infectious respiratory secretions:
  - Instruct persons who have “flu-like” symptoms (see below) to use respiratory hygiene/cough etiquette (See Box 2).
  - Promote use of masks<sup>4</sup> by symptomatic persons in common areas (e.g., waiting rooms in physician offices or emergency departments) or when being transported (e.g., in emergency vehicles).

**Symptoms of influenza** include fever, headache, myalgia, prostration, coryza, sore throat, and cough. Otitis media, nausea, and vomiting are also commonly reported among children. Typical influenza (or “flu-like”) symptoms, such as fever, may not always be present in elderly patients, young children, patients in long-term care facilities, or persons with underlying chronic illnesses (see **Supplement 5, Box 2**).

<sup>2</sup> During the early stages of a pandemic, laboratory-confirmation of influenza infection is recommended when possible.

<sup>3</sup> Surgical masks come in two basic types: one type is affixed to the head with two ties, conforms to the face with the aid of a flexible adjustment for the nose bridge, and may be flat/pleated or duck-billed in shape; the second type of surgical mask is pre-molded, adheres to the head with a single elastic and has a flexible adjustment for the nose bridge. Procedure masks are flat/pleated and affix to the head with ear loops. All masks have some degree of fluid resistance but those approved as surgical masks must meet specified standards for protection from penetration of blood and body fluids.

<sup>4</sup> Coughing persons may wear either a surgical or procedure mask. However, only procedure masks come in both adult and pediatric sizes.



## B. Management of infectious patients

### 1. Respiratory hygiene/cough etiquette

Respiratory hygiene/cough etiquette has been promoted as a strategy to contain respiratory viruses at the source and to limit their spread in areas where infectious patients might be awaiting medical care (e.g., physician offices, emergency departments) (see S4-IV.B.2).

The impact of covering sneezes and coughs and/or placing a mask on a coughing patient on the containment of respiratory secretions or on the transmission of respiratory infections has not been systematically studied. In theory, however, any measure that limits the dispersal of respiratory droplets should reduce the opportunity for transmission. Masking may be difficult in some settings, e.g., pediatrics, in which case the emphasis will be on cough hygiene.

The elements of respiratory hygiene/cough etiquette include:

- Education of healthcare facility staff, patients, and visitors on the importance of containing respiratory secretions to help prevent the transmission of influenza and other respiratory viruses
- Posted signs in languages appropriate to the populations served with instructions to patients and accompanying family members or friends to immediately report symptoms of a respiratory infection as directed
- Source control measures (e.g., covering the mouth/nose with a tissue when coughing and disposing of used tissues; using masks on the coughing person when they can be tolerated and are appropriate)
- Hand hygiene after contact with respiratory secretions, and
- Spatial separation, ideally >3 feet, of persons with respiratory infections in common waiting areas when possible.

### 2. Droplet precautions and patient placement

Patients with known or suspected pandemic influenza should be placed on droplet precautions for a minimum of 5 days from the onset of symptoms. Because immunocompromised patients may shed virus for longer periods, they may be placed on droplet precautions for the duration of their illness. Healthcare personnel should wear appropriate PPE (see S4-IV.C). The placement of patients will vary depending on the healthcare setting (see setting-specific guidance).

If the pandemic virus is associated with diarrhea, contact precautions (i.e., gowns and gloves for all patient contact) should be added.

CDC will update these recommendations if changes occur in the anticipated pattern of transmission ([www.cdc.gov/flu](http://www.cdc.gov/flu)).

## C. Infection control practices for healthcare personnel

Infection control practices for pandemic influenza are the same as for other human influenza viruses and primarily involve the application of standard and droplet precautions (Box 1) during patient care in healthcare settings (e.g., hospitals, nursing homes, outpatient offices, emergency transport vehicles). This guidance also applies to healthcare personnel going into the homes of patients. During a pandemic, conditions that could affect infection control may include shortages of antiviral drugs, decreased efficacy of the vaccine, increased virulence of the influenza strain, shortages of single-patient rooms, and shortages of personal protective equipment. These issues may necessitate changes in the standard recommended infection control practices for influenza. CDC will provide updated infection control guidance as circumstances dictate. Additional guidance is provided for family members providing home care (S4-IV.G) and for use in public settings (e.g., schools, workplace) where people with pandemic influenza may be encountered (S4-V and S4-VI).

## 1. Personal protective equipment

### a) PPE for standard and droplet precautions

PPE is used to prevent direct contact with the pandemic influenza virus. PPE that may be used to provide care includes surgical or procedure masks, as recommended for droplet precautions, and gloves and gowns, as recommended for standard precautions (Box 1). Additional precautions may be indicated during the performance of aerosol-generating procedures (see below). Information on the selection and use of PPE is provided at [www.cdc.gov/ncidod/hip/isolat/isolat.htm/](http://www.cdc.gov/ncidod/hip/isolat/isolat.htm/).

- **Masks (surgical or procedure)**
  - Wear a mask when entering a patient's room. A mask should be worn once and then discarded. If pandemic influenza patients are cohorted in a common area or in several rooms on a nursing unit, and multiple patients must be visited over a short time, it may be practical to wear one mask for the duration of the activity; however, other PPE (e.g., gloves, gown) must be removed between patients and hand hygiene performed.
  - Change masks when they become moist.
  - Do not leave masks dangling around the neck.
  - Upon touching or discarding a used mask, perform hand hygiene.
- **Gloves**
  - A single pair of patient care gloves should be worn for contact with blood and body fluids, including during hand contact with respiratory secretions (e.g., providing oral care, handling soiled tissues). Gloves made of latex, vinyl, nitrile, or other synthetic materials are appropriate for this purpose; if possible, latex-free gloves should be available for healthcare workers who have latex allergy.
  - Gloves should fit comfortably on the wearer's hands.
  - Remove and dispose of gloves after use on a patient; do not wash gloves for subsequent reuse.
  - Perform hand hygiene after glove removal.
  - If gloves are in short supply (i.e., the demand during a pandemic could exceed the supply), priorities for glove use might need to be established. In this circumstance, reserve gloves for situations where there is a likelihood of extensive patient or environmental contact with blood or body fluids, including during suctioning.
  - Use other barriers (e.g., disposable paper towels, paper napkins) when there is only limited contact with a patient's respiratory secretions (e.g., to handle used tissues). Hand hygiene should be strongly reinforced in this situation.
- **Gowns**
  - Wear an isolation gown, if soiling of personal clothes or uniform with a patient's blood or body fluids, including respiratory secretions, is anticipated. **Most patient interactions do not necessitate the use of gowns.** However, procedures such as intubation and activities that involve holding the patient close (e.g., in pediatric settings) are examples of when a gown may be needed when caring for pandemic influenza patients.
  - A disposable gown made of synthetic fiber or a washable cloth gown may be used.
  - Ensure that gowns are of the appropriate size to fully cover the area to be protected.
  - Gowns should be worn only once and then placed in a waste or laundry receptacle, as appropriate, and hand hygiene performed.
  - If gowns are in short supply (i.e., the demand during a pandemic could exceed the supply) priorities for their use may need to be established. In this circumstance, reinforcing the situations in which they are needed can reduce the volume used. Alternatively, other coverings (e.g., patient gowns) could be used. It is doubtful that disposable aprons would provide the desired protection in the circumstances where gowns are needed to prevent contact with

influenza virus, and therefore should be avoided. There are no data upon which to base a recommendation for reusing an isolation gown on the same patient. To avoid possible contamination, it is prudent to limit this practice.

- **Goggles or face shield**

In general, wearing goggles or a face shield for routine contact with patients with pandemic influenza is not necessary. If sprays or splatter of infectious material is likely, goggles or a face shield should be worn as recommended for standard precautions. Additional information related to the use of eye protection for infection control can be found at <http://www.cdc.gov/niosh/topics/eye/eye-infectious.html>.

#### **b) PPE for special circumstances**

- **PPE for aerosol-generating procedures**

During procedures that may generate increased small-particle aerosols of respiratory secretions (e.g., endotracheal intubation, nebulizer treatment, bronchoscopy, suctioning), healthcare personnel should wear gloves, gown, face/eye protection, and a N95 respirator or other appropriate particulate respirator. Respirators should be used within the context of a respiratory protection program that includes fit-testing, medical clearance, and training. If possible, and when practical, use of an airborne isolation room may be considered when conducting aerosol-generating procedures.

- **PPE for managing pandemic influenza with increased transmissibility**

The addition of airborne precautions, including respiratory protection (an N95 filtering face piece respirator or other appropriate particulate respirator), may be considered for strains of influenza exhibiting increased transmissibility, during initial stages of an outbreak of an emerging or novel strain of influenza, and as determined by other factors such as vaccination/immune status of personnel and availability of antivirals. As the epidemiologic characteristics of the pandemic virus are more clearly defined, CDC will provide updated infection control guidance, as needed.

- **Precautions for early stages of a pandemic**

Early in a pandemic, it may not be clear that a patient with severe respiratory illness has pandemic influenza. Therefore precautions consistent with all possible etiologies, including a newly emerging infectious agent, should be implemented. This may involve the combined use of airborne and contact precautions, in addition to standard precautions, until a diagnosis is established.

#### **c) Caring for patients with pandemic influenza**

Healthcare personnel should be particularly vigilant to avoid:

- Touching their eyes, nose or mouth with contaminated hands (gloved or ungloved). Careful placement of PPE before patient contact will help avoid the need to make PPE adjustments and risk self-contamination during use. Careful removal of PPE is also important. (See also: <http://www.cdc.gov/ncidod/hip/ppe/default.htm>.)
- Contaminating environmental surfaces that are not directly related to patient care (e.g., door knobs, light switches)

## **2. Hand hygiene**

Hand hygiene has frequently been cited as the single most important practice to reduce the transmission of infectious agents in healthcare settings (see <http://www.cdc.gov/handhygiene/pressrelease.htm>) and is an essential element of standard precautions. The term "hand hygiene" includes both handwashing with either plain or antimicrobial soap and water and use of alcohol-based products (gels, rinses, foams) containing an emollient that do not require the use of water.

- If hands are visibly soiled or contaminated with respiratory secretions, wash hands with soap (either non-antimicrobial or antimicrobial) and water.

- In the absence of visible soiling of hands, approved alcohol-based products for hand disinfection are preferred over antimicrobial or plain soap and water because of their superior microbiocidal activity, reduced drying of the skin, and convenience.
- Always perform hand hygiene between patient contacts and after removing PPE.
- Ensure that resources to facilitate handwashing (i.e., sinks with warm and cold running water, plain or antimicrobial soap, disposable paper towels) and hand disinfection (i.e., alcohol-based products) are readily accessible in areas in which patient care is provided. For additional guidance on hand hygiene see <http://www.cdc.gov/handhygiene/>.

### 3. Disposal of solid waste

Standard precautions are recommended for disposal of solid waste (medical and non-medical) that might be contaminated with a pandemic influenza virus:

- Contain and dispose of contaminated medical waste in accordance with facility-specific procedures and/or local or state regulations for handling and disposal of medical waste, including used needles and other sharps, and non-medical waste.
- Discard as routine waste used patient-care supplies that are not likely to be contaminated (e.g., paper wrappers).
- Wear disposable gloves when handling waste. Perform hand hygiene after removal of gloves.

### 4. Linen and laundry

Standard precautions are recommended for linen and laundry that might be contaminated with respiratory secretions from patients with pandemic influenza:

- Place soiled linen directly into a laundry bag in the patient's room. Contain linen in a manner that prevents the linen bag from opening or bursting during transport and while in the soiled linen holding area.
- Wear gloves and gown when directly handling soiled linen and laundry (e.g., bedding, towels, personal clothing) as per standard precautions. Do not shake or otherwise handle soiled linen and laundry in a manner that might create an opportunity for disease transmission or contamination of the environment.
- Wear gloves for transporting bagged linen and laundry.
- Perform hand hygiene after removing gloves that have been in contact with soiled linen and laundry.
- Wash and dry linen according to routine standards and procedures ([www.cdc.gov/ncidod/hip/enviro/guide.htm](http://www.cdc.gov/ncidod/hip/enviro/guide.htm)).

### 5. Dishes and eating utensils

Standard precautions are recommended for handling dishes and eating utensils used by a patient with known or possible pandemic influenza:

- Wash reusable dishes and utensils in a dishwasher with recommended water temperature ([www.cdc.gov/ncidod/hip/enviro/guide.htm](http://www.cdc.gov/ncidod/hip/enviro/guide.htm)).
- Disposable dishes and utensils (e.g., used in an alternative care site set-up for large numbers of patients) should be discarded with other general waste.
- Wear gloves when handling patient trays, dishes, and utensils.

### 6. Patient-care equipment

Follow standard practices for handling and reprocessing used patient-care equipment, including medical devices:

- Wear gloves when handling and transporting used patient-care equipment.

- Wipe heavily soiled equipment with an EPA-approved hospital disinfectant before removing it from the patient's room. Follow current recommendations for cleaning and disinfection or sterilization of reusable patient-care equipment.
- Wipe external surfaces of portable equipment for performing x-rays and other procedures in the patient's room with an EPA-approved hospital disinfectant upon removal from the patient's room.

## 7. Environmental cleaning and disinfection

Cleaning and disinfection of environmental surfaces are important components of routine infection control in healthcare facilities. Environmental cleaning and disinfection for pandemic influenza follow the same general principles used in healthcare settings.

### a) Cleaning and disinfection of patient-occupied rooms

(See: [www.cdc.gov/ncidod/hip/enviro/Enviro\\_guide\\_03.pdf](http://www.cdc.gov/ncidod/hip/enviro/Enviro_guide_03.pdf) )

- Wear gloves in accordance with facility policies for environmental cleaning and wear a surgical or procedure mask in accordance with droplet precautions. Gowns are not necessary for routine cleaning of an influenza patient's room.
- Keep areas around the patient free of unnecessary supplies and equipment to facilitate daily cleaning.
- Use any EPA-registered hospital detergent-disinfectant. Follow manufacturer's recommendations for use-dilution (i.e., concentration), contact time, and care in handling.
- Follow facility procedures for regular cleaning of patient-occupied rooms. Give special attention to frequently touched surfaces (e.g., bedrails, bedside and over-bed tables, TV controls, call buttons, telephones, lavatory surfaces including safety/pull-up bars, doorknobs, commodes, ventilator surfaces) in addition to floors and other horizontal surfaces.
- Clean and disinfect spills of blood and body fluids in accordance with current recommendations for Isolation Precautions ([www.cdc.gov/ncidod/hip/ISOLAT/Isolat.htm](http://www.cdc.gov/ncidod/hip/ISOLAT/Isolat.htm)).

### b) Cleaning and disinfection after patient discharge or transfer

- Follow standard facility procedures for post-discharge cleaning of an isolation room.
- Clean and disinfect all surfaces that were in contact with the patient or might have become contaminated during patient care. No special treatment is necessary for window curtains, ceilings, and walls unless there is evidence of visible soiling.
- Do not spray (i.e., fog) occupied or unoccupied rooms with disinfectant. This is a potentially dangerous practice that has no proven disease control benefit.

## 8. Postmortem care

Follow standard facility practices for care of the deceased. Practices should include standard precautions for contact with blood and body fluids.

## 9. Laboratory specimens and practices

Follow standard facility and laboratory practices for the collection, handling, and processing of laboratory specimens.

## D. Occupational health issues

Healthcare personnel are at risk for pandemic influenza through community and healthcare-related exposures. Once pandemic influenza has reached a community, healthcare facilities must implement systems to monitor for illness in the facility workforce and manage those who are symptomatic or ill.

- Implement a system to educate personnel about occupational health issues related to pandemic influenza.
- Screen all personnel for influenza-like symptoms before they come on duty. Symptomatic personnel should be sent home until they are physically ready to return to duty.
- Healthcare personnel who have recovered from pandemic influenza, and should develop antibody against future infection with the same virus, and therefore should be prioritized for the care of patients with active pandemic influenza and its complications. These workers would also be well suited to care for patients who are at risk for serious complications from influenza (e.g., transplant patients and neonates).
- Personnel who are at high risk for complications of pandemic influenza (e.g., pregnant women, immunocompromised persons) should be informed about their medical risk and offered an alternate work assignment, away from influenza-patient care, or considered for administrative leave until pandemic influenza has abated in the community.

## E. Reducing exposure of persons at high risk for complications of influenza

Persons who are well, but at high risk for influenza or its complications (e.g., persons with underlying diseases), should be instructed to avoid unnecessary contact with healthcare facilities caring for pandemic influenza patients (i.e., do not visit patients, postpone nonessential medical care).

## F. Healthcare setting-specific guidance

All healthcare facilities should follow the infection control guidance in S4-IV.A-E above. The following guidance is intended to address setting-specific infection control issues that should also be considered.

### 1. Hospitals

#### a) Detection of persons entering the facility who may have pandemic influenza

- Post visual alerts (in appropriate languages) at the entrance to hospital outpatient facilities (e.g., emergency departments, outpatient clinics) instructing persons with respiratory symptoms (e.g., patients, persons who accompany them) to:
  - Inform reception and healthcare personnel when they first register for care, and
  - Practice respiratory hygiene/cough etiquette (see [www.cdc.gov/flu/professionals/infectioncontrol/resphygiene.htm](http://www.cdc.gov/flu/professionals/infectioncontrol/resphygiene.htm)).
 Sample visual alerts are available on CDC's SARS website: <http://www.cdc.gov/ncidod/hip/INFECT/RespiratoryPoster.pdf>
- Triage patients calling for medical appointments for influenza symptoms:
  - Discourage unnecessary visits to medical facilities.
  - Instruct symptomatic patients on infection control measures to limit transmission in the home and when traveling to necessary medical appointments.

As the scope of the pandemic escalates locally, consider setting up a separate triage area for persons presenting with symptoms of respiratory infection. Because not every patient presenting with symptoms will have pandemic influenza, infection control measures will be important in preventing further spread.

- During the peak of a pandemic, emergency departments and outpatient offices may be overwhelmed with patients seeking care. A "triage officer" may be useful for managing patient flow, including deferral of patients who do not require emergency care.
- Designate separate waiting areas for patients with influenza-like symptoms. If this is not feasible, the waiting area should be set up to enable patients with respiratory symptoms to sit as far away as possible (at least 3 feet) from other patients.

**b) "Source control" measures to limit dissemination of influenza virus from respiratory secretions**

- Post signs that promote respiratory hygiene/cough etiquette in common areas (e.g., elevators, waiting areas, cafeterias, lavatories) where they can serve as reminders to all persons in the healthcare facility. Signs should instruct persons to:
  - Cover the nose/mouth when coughing or sneezing.
  - Use tissues to contain respiratory secretions.
  - Dispose of tissues in the nearest waste receptacle after use.
  - Perform hand hygiene after contact with respiratory secretions.
 Samples of visual alerts are available on CDC's SARS website: <http://www.cdc.gov/ncidod/hip/INFECT/RespiratoryPoster.pdf>
- Facilitate adherence to respiratory hygiene/cough etiquette by ensuring the availability of materials in waiting areas for patients and visitors.
  - Provide tissues and no-touch receptacles (e.g., waste containers with pedal-operated lid or uncovered waste container) for used tissue disposal.
  - Provide conveniently located dispensers of alcohol-based hand rub.
  - Provide soap and disposable towels for handwashing where sinks are available.
- Promote the use of masks and spatial separation by persons with symptoms of influenza.
  - Offer and encourage the use of either procedure masks (i.e., with ear loops) or surgical masks (i.e., with ties or elastic) by symptomatic persons to limit dispersal of respiratory droplets.
  - Encourage coughing persons to sit as far away as possible (at least 3 feet) from other persons in common waiting areas.

**c) Hospitalization of pandemic influenza patients**

- Patient placement
  - Limit admission of influenza patients to those with severe complications of influenza who cannot be cared for outside the hospital setting.
  - Admit patients to either a single-patient room or an area designated for cohorting of patients with influenza.
- Cohorting
  - Designated units or areas of a facility should be used for cohorting patients with pandemic influenza.<sup>6</sup> During a pandemic, other respiratory viruses (e.g., non-pandemic influenza, respiratory syncytial virus, parainfluenza virus) may be circulating concurrently in a community. Therefore, to prevent cross-transmission of respiratory viruses, whenever possible assign only patients with confirmed pandemic influenza to the same room. At the height of a pandemic, laboratory testing to confirm pandemic influenza is likely to be limited, in which case cohorting should be based on having symptoms consistent with pandemic influenza.
  - Personnel (clinical and non-clinical) assigned to cohorted patient care units for pandemic influenza patients should not "float" or otherwise be assigned to other patient care areas. The number of personnel entering the cohorted area should be limited to those necessary for patient care and support.
  - Personnel assigned to cohorted patient care units should be aware that patients with pandemic influenza may be concurrently infected or colonized with other pathogenic organisms (e.g., *Staphylococcus aureus*, *Clostridium*

<sup>6</sup> During the early stages of a pandemic, laboratory-confirmation of influenza infection is recommended when possible before cohorting patients.



*difficile*) and should adhere to infection control practices (e.g., hand hygiene, changing gloves between patient contact) used routinely, and as part of standard precautions, to prevent nosocomial transmission.

- Because of the high patient volume anticipated during a pandemic, cohorting should be implemented early in the course of a local outbreak.
- Patient transport
  - Limit patient movement and transport outside the isolation area to medically necessary purposes.
  - Consider having portable x-ray equipment available in areas designated for cohorting influenza patients.
  - If transport or movement is necessary, ensure that the patient wears a surgical or procedure mask. If a mask cannot be tolerated (e.g., due to the patient's age or deteriorating respiratory status), apply the most practical measures to contain respiratory secretions. Patients should perform hand hygiene before leaving the room.
- Visitors
  - Screen visitors for signs and symptoms of influenza before entry into the facility and exclude persons who are symptomatic.
  - Family members who accompany patients with influenza-like illness to the hospital are assumed to have been exposed to influenza and should wear masks.
  - Limit visitors to persons who are necessary for the patient's emotional well-being and care.
  - Instruct visitors to wear surgical or procedure masks while in the patient's room.
  - Instruct visitors on hand-hygiene practices.

#### d) Control of nosocomial pandemic influenza transmission

- Once patients with pandemic influenza are admitted to the hospital, nosocomial surveillance should be heightened for evidence of transmission to other patients and healthcare personnel. (Once pandemic influenza is firmly established in a community this may not be feasible or necessary.)
- If limited nosocomial transmission is detected (e.g., has occurred on one or two patient care units), appropriate control measures should be implemented. These may include:
  - Cohorting of patients and staff on affected units
  - Restriction of new admissions (except for other pandemic influenza patients) to the affected unit(s)
  - Restriction of visitors to the affected unit(s) to those who are essential for patient care and support
- If widespread nosocomial transmission occurs, controls may need to be implemented hospital wide and might include:
  - Restricting all nonessential persons
  - Stopping admissions not related to pandemic influenza and stopping elective surgeries

## 2. Nursing homes and other residential facilities

Residents of nursing homes and other residential facilities will be at particular risk for transmission of pandemic influenza and disease complications. Pandemic influenza can be introduced through facility personnel and visitors; once a pandemic influenza virus enters such facilities, controlling its spread is problematic. Therefore, as soon as pandemic influenza has been detected in the region, nursing homes and other residential facilities should implement aggressive measures to prevent introduction of the virus.

**a) Prevention or delay of pandemic influenza virus entry into the facility**

- Control of visitors
  - Post visual alerts (in appropriate languages) at the entrance to the facility restricting entry by persons who have been exposed to or have symptoms of pandemic influenza.
  - Enforce visitor restrictions by assigning personnel to verbally and visually screen visitors for respiratory symptoms at points of entry to the facility.
  - Provide a telephone number where persons can call for information on measures used to prevent the introduction of pandemic influenza.
- Control of personnel
  - Implement a system to screen all personnel for influenza-like symptoms before they come on duty. Symptomatic personnel should be sent home until they are physically able to return to duty.

**b) Monitoring patients for pandemic influenza and instituting appropriate control measures**

Despite aggressive efforts to prevent the introduction of pandemic influenza virus, persons in the early stages of pandemic influenza could introduce it to the facility. Residents returning from a hospital stay, outpatient visit, or family visit could also introduce the virus. Early detection of the presence of pandemic influenza in a facility is critical for ensuring timely implementation of infection control measures.

- Early in the progress of a pandemic in the region, increase resident surveillance for influenza-like symptoms. Notify state or local health department officials if a case(s) is suspected.
- If symptoms of pandemic influenza are apparent (see **Supplement 5**), implement droplet precautions for the resident and roommates, pending confirmation of pandemic influenza virus infection. Patients and roommates should not be separated or moved out of their rooms unless medically necessary. Once a patient has been diagnosed with pandemic influenza, roommates should be treated as exposed cohorts.
- Cohort residents and staff *on units with known or suspected cases of pandemic influenza*.
- Limit movement within the facility (e.g., temporarily close the dining room and serve meals on nursing units, cancel social and recreational activities).

**3. Prehospital care (emergency medical services)**

Patients with severe pandemic influenza or disease complications are likely to require emergency transport to the hospital. The following information is designed to protect EMS personnel during transport.

- Screen patients requiring emergency transport for symptoms of influenza.
- Follow standard and droplet precautions when transporting symptomatic patients.
- Consider routine use of surgical or procedure masks for all patient transport when pandemic influenza is in the community.
- If possible, place a procedure or surgical mask on the patient to contain droplets expelled during coughing. If this is not possible (i.e., would further compromise respiratory status, difficult for the patient to wear), have the patient cover the mouth/nose with tissue when coughing, or use the most practical alternative to contain respiratory secretions.
- Oxygen delivery with a non-rebreather face mask can be used to provide oxygen support during transport. If needed, positive-pressure ventilation should be performed using a resuscitation bag-valve mask.
- Unless medically necessary to support life, aerosol-generating procedures (e.g., mechanical ventilation) should be avoided during prehospital care.

- Optimize the vehicle's ventilation to increase the volume of air exchange during transport. When possible, use vehicles that have separate driver and patient compartments that can provide separate ventilation to each area.
- Notify the receiving facility that a patient with possible pandemic influenza is being transported.
- Follow standard operating procedures for routine cleaning of the emergency vehicle and reusable patient care equipment.

#### 4. Home healthcare services

Home healthcare includes health and rehabilitative services performed in the home by providers including home health agencies, hospices, durable medical equipment providers, home infusion therapy services, and personal care and support services staff. The scope of services ranges from assistance with activities of daily living and physical and occupational therapy to wound care, infusion therapy, and chronic ambulatory peritoneal dialysis (CAPD). Communication between home healthcare providers and patients or their family members is essential for ensuring that these personnel are appropriately protected.

When pandemic influenza is in the community, home health agencies should consider contacting patients before the home visit to determine whether persons in the household have an influenza-like illness.

- If patients with pandemic influenza are in the home, consider:
  - Postponing nonessential services
  - Assigning providers who are not at increased risk for complications of pandemic influenza to care for these patients
- Home healthcare providers who enter homes where there is a person with an influenza-like illness should follow the recommendations for standard and droplet precautions described above. Professional judgment should be used in determining whether to don a surgical or procedure mask upon entry into the home or only for patient interactions. Factors to consider include the possibility that others in the household may be infectious and the extent to which the patient is ambulating within the home.

#### 5. Outpatient medical offices

Patients with nonemergency symptoms of an influenza-like illness may seek care from their medical provider. Implementation of infection control measures when these patients present for care will help prevent exposure among other patients and clinical and nonclinical office staff.

##### a) Detection of patients with possible pandemic influenza

- Post visual alerts (in appropriate languages) at the entrance to outpatient offices instructing persons with respiratory symptoms (e.g., patients, persons who accompany them) to:
  - Inform reception and healthcare personnel when they first register for care
  - Practice respiratory hygiene/cough etiquette (see [www.cdc.gov/flu/professionals/infectioncontrol/resphygiene.htm](http://www.cdc.gov/flu/professionals/infectioncontrol/resphygiene.htm))
 Sample visual alerts may be found on CDC's SARS website: <http://www.cdc.gov/ncidod/hip/INFECT/RespiratoryPoster.pdf>
- Triage patients calling for medical appointments for influenza symptoms:
  - Discourage unnecessary visits to medical facilities.
  - Instruct symptomatic patients on infection control measures to limit transmission in the home and when traveling to necessary medical appointments.

##### b) "Source control" measures

- Post signs that promote cough etiquette in common areas (e.g., elevators, waiting areas, cafeterias, lavatories) where they can serve as reminders to all persons in the healthcare facility. Signs should instruct persons to:

- Cover the nose/mouth when coughing or sneezing.
- Use tissues to contain respiratory secretions.
- Dispose of tissues in the nearest waste receptacle after use.
- Perform hand hygiene after contact with respiratory secretions.
- Facilitate adherence to respiratory hygiene/cough etiquette. Ensure the availability of materials in waiting areas for patients and visitors.
  - Provide tissues and no-touch receptacles (e.g., waste containers with pedal-operated lid or uncovered waste container) for used tissue disposal.
  - Provide conveniently located dispensers of alcohol-based hand rub.
  - Provide soap and disposable towels for hand washing where sinks are available.
- Promote the use of procedure or surgical masks and spatial separation by persons with symptoms of influenza.
  - Offer and encourage the use of either procedure masks (i.e., with ear loops) or surgical masks (i.e., with ties or elastic) by symptomatic persons to limit dispersal of respiratory droplets.
  - Encourage coughing persons to sit at least 3 feet away from other persons in common waiting areas.

#### c) Patient placement

- Where possible, designate separate waiting areas for patients with symptoms of pandemic influenza. Place signs indicating the separate waiting areas.
- Place symptomatic patients in an evaluation room as soon as possible to limit their time in common waiting areas.

## 6. Other ambulatory settings

A wide variety of ambulatory settings provide chronic (e.g., hemodialysis units) and episodic (e.g., freestanding surgery centers, dental offices) healthcare services. When pandemic influenza is in the region, these facilities should implement control measures similar to those recommended for outpatient physician offices. Other infection control strategies that may be utilized include:

- Screening patients for influenza-like illness by phone or before coming into the facility and rescheduling appointments for those whose care is nonemergency
- Canceling all nonemergency services when there is pandemic influenza in the community

## G. Care of pandemic influenza patients in the home

Most patients with pandemic influenza will be able to remain at home during the course of their illness and can be cared for by other family members or others who live in the household. Anyone residing in a household with an influenza patient during the incubation period and illness is at risk for developing influenza. A key objective in this setting is to limit transmission of pandemic influenza within and outside the home. When care is provided by a household member, basic infection control precautions should be emphasized (e.g., segregating the ill patient, hand hygiene). Infection within the household may be minimized if a primary caregiver is designated, ideally someone who does not have an underlying condition that places them at increased risk of severe influenza disease. Although no studies have assessed the use of masks at home to decrease the spread of infection, use of surgical or procedure masks by the patient and/or caregiver during interactions may be of benefit.

### 1. Management of influenza patients

- Physically separate the patient with influenza from non-ill persons living in the home as much as possible.
- Patients should not leave the home during the period when they are most likely to be infectious to others (i.e., 5 days after onset of symptoms). When movement outside the home is necessary (e.g., for medical care), the patient should

follow cough etiquette (i.e., cover the mouth and nose when coughing and sneezing) and wear procedure or surgical masks if available.

## 2. Management of other persons in the home

- Persons who have not been exposed to pandemic influenza and who are not essential for patient care or support should not enter the home while persons are actively ill with pandemic influenza.
- If unexposed persons must enter the home, they should avoid close contact with the patient.
- Persons living in the home with the pandemic influenza patient should limit contact with the patient to the extent possible; consider designating one person as the primary care provider.
- Household members should monitor closely for the development of influenza symptoms and contact a telephone hotline or medical care provider if symptoms occur.

## 3. Infection control measures in the home

- All persons in the household should carefully follow recommendations for hand hygiene (i.e., handwashing with soap and water or use of an alcohol-based hand rub) after contact with an influenza patient or the environment in which care is provided.
- Although no studies have assessed the use of masks at home to decrease the spread of infection, use of surgical or procedure masks by the patient and/or caregiver during interactions may be of benefit. The wearing of gloves and gowns is not recommended for household members providing care in the home.
- Soiled dishes and eating utensils should be washed either in a dishwasher or by hand with warm water and soap. Separation of eating utensils for use by a patient with influenza is not necessary.
- Laundry can be washed in a standard washing machine with warm or cold water and detergent. It is not necessary to separate soiled linen and laundry used by a patient with influenza from other household laundry. Care should be used when handling soiled laundry (i.e., avoid "hugging" the laundry) to avoid contamination. Hand hygiene should be performed after handling soiled laundry.
- Tissues used by the ill patient should be placed in a bag and disposed with other household waste. Consider placing a bag for this purpose at the bedside.
- Normal cleaning of environmental surfaces in the home should be followed.

## H. Care of pandemic influenza patients at alternative sites

If an influenza pandemic results in severe illness that overwhelms the capacity of existing healthcare resources, it may become necessary to provide care at alternative sites (e.g., schools, auditoriums, conference centers, hotels). Existing "all-hazard" plans have likely identified designated sites for this purpose. The same principles of infection control apply in these settings as in other healthcare settings. Careful planning is necessary to ensure that resources are available and procedures are in place to adhere to the key principles of infection control.

## S4-V. RECOMMENDATIONS FOR INFECTION CONTROL IN SCHOOLS AND WORKPLACES

- In schools and workplaces, infection control for pandemic influenza should focus on:
  - Keeping sick students, faculty, and workers away while they are infectious.
  - Promoting respiratory hygiene/cough etiquette and hand hygiene as for any respiratory infection.

The benefit of wearing masks in these settings has not been established.

- School administrators and employers should ensure that materials for respiratory hygiene/cough etiquette (i.e., tissues and receptacles for their disposal) and hand hygiene are available. Educational messages and infection control guidance for pandemic influenza are available for distribution. (CDC will develop educational materials appropriate to various audiences.)

## **S4-VI. RECOMMENDATIONS FOR INFECTION CONTROL IN COMMUNITY SETTINGS**

Infection control in the community should focus on “social distancing” and promoting respiratory hygiene/cough etiquette and hand hygiene to decrease exposure to others. This could include the use of masks by persons with respiratory symptoms, if feasible. Although the use of masks in community settings has not been demonstrated to be a public health measure to decrease infections during a community outbreak, persons may choose to wear a mask as part of individual protection strategies that include cough etiquette, hand hygiene, and avoiding public gatherings. Mask use may also be important for persons who are at high risk for complications of influenza. Public education should be provided on how to use masks appropriately. Persons at high risk for complications of influenza should try to avoid public gatherings (e.g., movies, religious services, public meetings) when pandemic influenza is in the community. They should also avoid going to other public areas (e.g., food stores, pharmacies); the use of other persons for shopping or home delivery service is encouraged.

## BOX 1. SUMMARY OF INFECTION CONTROL RECOMMENDATIONS FOR CARE OF PATIENTS WITH PANDEMIC INFLUENZA

| COMPONENT                                                                                                                                                                                               | RECOMMENDATIONS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| STANDARD PRECAUTIONS                                                                                                                                                                                    | See <a href="http://www.cdc.gov/ncidod/hip/ISOLAT/std_prec_excerpt.htm">www.cdc.gov/ncidod/hip/ISOLAT/std_prec_excerpt.htm</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Hand hygiene                                                                                                                                                                                            | Perform hand hygiene after touching blood, body fluids, secretions, excretions, and contaminated items; after removing gloves; and between patient contacts. Hand hygiene includes both handwashing with either plain or antimicrobial soap and water or use of alcohol-based products (gels, rinses, foams) that contain an emollient and do not require the use of water. If hands are visibly soiled or contaminated with respiratory secretions, they should be washed with soap (either non-antimicrobial or antimicrobial) and water. In the absence of visible soiling of hands, approved alcohol-based products for hand disinfection are preferred over antimicrobial or plain soap and water because of their superior microbicidal activity, reduced drying of the skin, and convenience. |
| Personal protective equipment (PPE) <ul style="list-style-type: none"> <li>Gloves</li> <li>Gown</li> <li>Face/eye protection (e.g., surgical or procedure mask and goggles or a face shield)</li> </ul> | <ul style="list-style-type: none"> <li>For touching blood, body fluids, secretions, excretions, and contaminated items; for touching mucous membranes and nonintact skin</li> <li>During procedures and patient-care activities when contact of clothing/exposed skin with blood/body fluids, secretions, and excretions is anticipated</li> <li>During procedures and patient care activities likely to generate splash or spray of blood, body fluids, secretions, excretions</li> </ul>                                                                                                                                                                                                                                                                                                           |
| Safe work practices                                                                                                                                                                                     | Avoid touching eyes, nose, mouth, or exposed skin with contaminated hands (gloved or ungloved); avoid touching surfaces with contaminated gloves and other PPE that are not directly related to patient care (e.g., door knobs, keys, light switches).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Patient resuscitation                                                                                                                                                                                   | Avoid unnecessary mouth-to-mouth contact; use mouthpiece, resuscitation bag, or other ventilation devices to prevent contact with mouth and oral secretions.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Soiled patient care equipment                                                                                                                                                                           | Handle in a manner that prevents transfer of microorganisms to oneself, others, and environmental surfaces; wear gloves if visibly contaminated; perform hand hygiene after handling equipment.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Soiled linen and laundry                                                                                                                                                                                | Handle in a manner that prevents transfer of microorganisms to oneself, others, and to environmental surfaces; wear gloves (gown if necessary) when handling and transporting soiled linen and laundry; and perform hand hygiene.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Needles and other sharps                                                                                                                                                                                | Use devices with safety features when available; do not recap, bend, break or hand-manipulate used needles; if recapping is necessary, use a one-handed scoop technique; place used sharps in a puncture-resistant container.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |



## **BOX 1. SUMMARY OF INFECTION CONTROL RECOMMENDATIONS FOR CARE OF PATIENTS WITH PANDEMIC INFLUENZA (CONT.)**

| COMPONENT                                                                                                                                                                                                              | RECOMMENDATIONS                                                                                                                                                                                                                                                                                                                                                                                         |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>STANDARD PRECAUTIONS (cont.)</b>                                                                                                                                                                                    | See <a href="http://www.cdc.gov/ncidod/hip/ISOLAT/std_prec_excerpt.htm">www.cdc.gov/ncidod/hip/ISOLAT/std_prec_excerpt.htm</a>                                                                                                                                                                                                                                                                          |
| Environmental cleaning and disinfection                                                                                                                                                                                | Use EPA-registered hospital detergent-disinfectant; follow standard facility procedures for cleaning and disinfection of environmental surfaces; emphasize cleaning/disinfection of frequently touched surfaces (e.g., bed rails, phones, lavatory surfaces).                                                                                                                                           |
| Disposal of solid waste                                                                                                                                                                                                | Contain and dispose of solid waste (medical and non-medical) in accordance with facility procedures and/or local or state regulations; wear gloves when handling waste; wear gloves when handling waste containers; perform hand hygiene.                                                                                                                                                               |
| Respiratory hygiene/cough etiquette<br>Source control measures for persons with symptoms of a respiratory infection; implement at first point of encounter (e.g., triage/reception areas) within a healthcare setting. | Cover the mouth/nose when sneezing/coughing; use tissues and dispose in no-touch receptacles; perform hand hygiene after contact with respiratory secretions; wear a mask (procedure or surgical) if tolerated; sit or stand as far away as possible (more than 3 feet) from persons who are not ill.                                                                                                   |
| <b>DROPLET PRECAUTIONS</b>                                                                                                                                                                                             | <a href="http://www.cdc.gov/ncidod/hip/ISOLAT/droplet_prec_excerpt.htm">www.cdc.gov/ncidod/hip/ISOLAT/droplet_prec_excerpt.htm</a>                                                                                                                                                                                                                                                                      |
| Patient placement                                                                                                                                                                                                      | Place patients with influenza in a private room or cohort with other patients with influenza.* Keep door closed or slightly ajar; maintain room assignments of patients in nursing homes and other residential settings; and apply droplet precautions to all persons in the room.<br><br>*During the early stages of a pandemic, infection with influenza should be laboratory-confirmed, if possible. |
| Personal protective equipment                                                                                                                                                                                          | Wear a surgical or procedure mask for entry into patient room; wear other PPE as recommended for standard precautions.                                                                                                                                                                                                                                                                                  |
| Patient transport                                                                                                                                                                                                      | Limit patient movement outside of room to medically necessary purposes; have patient wear a procedure or surgical mask when outside the room.                                                                                                                                                                                                                                                           |
| Other                                                                                                                                                                                                                  | Follow standard precautions and facility procedures for handling linen and laundry and dishes and eating utensils, and for cleaning/disinfection of environmental surfaces and patient care equipment, disposal of solid waste, and postmortem care.                                                                                                                                                    |
| <b>AEROSOL-GENERATING PROCEDURES</b>                                                                                                                                                                                   | During procedures that may generate small particles of respiratory secretions (e.g., endotracheal intubation, bronchoscopy, nebulizer treatment, suctioning), healthcare personnel should wear gloves, gown, face/eye protection, and a fit-tested N95 respirator or other appropriate particulate respirator.                                                                                          |

## **BOX 2. RESPIRATORY HYGIENE/COUGH ETIQUETTE**

To contain respiratory secretions, all persons with signs and symptoms of a respiratory infection, regardless of presumed cause, should be instructed to:

- Cover the nose/mouth when coughing or sneezing.
- Use tissues to contain respiratory secretions.
- Dispose of tissues in the nearest waste receptacle after use.
- Perform hand hygiene after contact with respiratory secretions and contaminated objects/materials.

Healthcare facilities should ensure the availability of materials for adhering to respiratory hygiene/cough etiquette in waiting areas for patients and visitors:

- Provide tissues and no-touch receptacles for used tissue disposal.
- Provide conveniently located dispensers of alcohol-based hand rub.
- Provide soap and disposable towels for handwashing where sinks are available.

### **Masking and separation of persons with symptoms of respiratory infection**

During periods of increased respiratory infection in the community, persons who are coughing should be offered either a procedure mask (i.e., with ear loops) or a surgical mask (i.e., with ties) to contain respiratory secretions. Coughing persons should be encouraged to sit as far away as possible (at least 3 feet) from others in common waiting areas. Some facilities may wish to institute this recommendation year-round.



# supplement 5 clinical guidelines

## TABLE OF CONTENTS

|                                                                                                                                                              |       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|
| SUMMARY OF PUBLIC HEALTH ROLES AND RESPONSIBILITIES FOR CLINICAL GUIDELINES .....                                                                            | S5-2  |
| S5-I. RATIONALE .....                                                                                                                                        | S5-3  |
| S5-II. OVERVIEW .....                                                                                                                                        | S5-3  |
| S5-III. CLINICAL GUIDELINES FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS.....                                                                            | S5-4  |
| A. Criteria for evaluation of patients with possible novel influenza .....                                                                                   | S5-4  |
| 1. Clinical criteria .....                                                                                                                                   | S5-5  |
| 2. Epidemiologic criteria.....                                                                                                                               | S5-5  |
| B. Initial management of patients who meet the criteria for novel influenza .....                                                                            | S5-6  |
| C. Management of patients who test positive for novel influenza.....                                                                                         | S5-8  |
| D. Management of patients who test positive for seasonal influenza .....                                                                                     | S5-8  |
| E. Management of patients who test negative for novel influenza .....                                                                                        | S5-8  |
| S5-IV. CLINICAL GUIDELINES FOR THE PANDEMIC PERIOD .....                                                                                                     | S5-8  |
| A. Criteria for evaluation of patients with possible pandemic influenza.....                                                                                 | S5-9  |
| 1. Clinical criteria .....                                                                                                                                   | S5-9  |
| 2. Epidemiologic criteria.....                                                                                                                               | S5-9  |
| B. Initial management of patients who meet the criteria for pandemic influenza .....                                                                         | S5-9  |
| C. Clinical management of pandemic influenza patients.....                                                                                                   | S5-10 |
| Box 1. Risk of Novel Influenza in Persons with Severe Respiratory Disease or Influenza-like Illness during the Interpandemic and Pandemic Alert Periods..... | S5-12 |
| Box 2. Clinical Evaluation of Patients with Influenza-like Illness during the Interpandemic and Pandemic Alert Periods .....                                 | S5-13 |
| Box 3. Special Situations and Exceptions to the Clinical Criteria .....                                                                                      | S5-14 |
| Box 4. Home Care Infection Control Guidance for Pandemic Influenza Patients and Household Members.....                                                       | S5-15 |
| Figure 1. Case Detection and Clinical Management during the Interpandemic and Pandemic Alert Periods.....                                                    | S5-16 |
| Figure 2. Case Detection and Clinical Management during the Pandemic Period .....                                                                            | S5-18 |
| Table 1. Pandemic Influenza Infection Control Guidance for Healthcare Providers .....                                                                        | S5-20 |
| Appendix 1. Clinical Presentation and Complications of Seasonal Influenza .....                                                                              | S5-23 |
| Appendix 2. Clinical Presentation and Complications of Illnesses Associated with Avian Influenza A (H5N1) and Previous Pandemic Influenza Viruses.....       | S5-27 |
| Appendix 3. Guidelines for Management of Community-acquired Pneumonia, Including Post-influenza Community-acquired Pneumonia .....                           | S5-29 |

## SUMMARY OF PUBLIC HEALTH ROLES AND RESPONSIBILITIES FOR CLINICAL GUIDELINES

### INTERPANDEMIC AND PANDEMIC ALERT PERIODS

#### Healthcare providers:

- Be aware of case definitions; procedures for screening, infection control, and laboratory testing; and antiviral regimens for influenza A (H5N1) and other novel influenza viruses.
- Notify health departments about suspected/confirmed novel influenza cases and fatalities.
- Collect recommended specimens for diagnosis of novel influenza, and forward specimens to designated state and federal laboratories.

#### State and local public health agencies:

- Help educate healthcare providers about novel and pandemic influenza.
- Provide or facilitate testing and investigation of suspected novel influenza cases.
- Conduct follow-up of suspected novel influenza cases.

#### HHS agencies:

- Develop and disseminate recommendations on the use of influenza diagnostic tests, antiviral drugs, and vaccines during a pandemic (see also Supplement 6 and Supplement 7).
- Develop a national stockpile of antiviral drugs for use during a pandemic (see also Supplement 6).
- Work with partner organizations to discuss and resolve clinical issues related to pandemic influenza response.
- Assist ministries of health and WHO in characterizing cases of human infection with avian influenza A (H5N1) or other novel strains of influenza, particularly with regard to antiviral susceptibility, transmission parameters, and clinical outcomes.
- Work with state and local health departments to investigate and manage suspected cases of human infection with avian influenza A (H5N1) or other novel strains of influenza.
- Establish case definition and reporting mechanisms.

### PANDEMIC PERIOD

#### Healthcare providers:

- Regularly consult updates on case definitions, screening, laboratory testing, and treatment algorithms for pandemic influenza.
- Report pandemic influenza cases or fatalities as requested by health departments.
- Collect recommended specimens for ongoing pandemic influenza surveillance, and forward specimens as requested to designated state and federal laboratories.
- Report atypical cases, breakthrough infections while on prophylaxis, or any other abnormal cases throughout the duration of the pandemic to public health agencies.

**State and local public health agencies:**

- Update providers regularly as the influenza pandemic unfolds.
- Provide or facilitate testing and investigation of pandemic influenza cases.
- Work with CDC to investigate and report special pandemic situations.

**HHS responsibilities:**

- Update and disseminate national guidelines on influenza diagnostic testing and use of antiviral drugs and vaccines during the pandemic.
- Develop a pandemic influenza vaccine (see also Part 1 and Supplement 6).
- Work with healthcare partners to refine clinical management guidelines and issue regular updates on treatment issues.
- Conduct observational and interventional studies with partner institutions to investigate pandemic influenza pathogenesis and develop disease prevention and treatment strategies.
- Monitor pandemic influenza cases for antiviral resistance and transmission parameters.
- Monitor antiviral drug use and inventories.
- Collect information on clinical features, outcomes, and treatments.

**S5-I. RATIONALE**

Healthcare providers play an essential role in the detection of an initial case of novel or pandemic influenza in a community. If implemented early, identification and isolation of cases may help slow the spread of influenza within a community. Clinical awareness of novel or pandemic influenza disease can also benefit the individual patient, as rapid diagnosis and initiation of treatment can avert potentially severe complications. Detection is complicated, however, by the lack of specific clinical findings and commercially available laboratory tests that can rapidly distinguish novel or pandemic influenza from seasonal influenza. In addition, neither the clinical characteristics of a novel or pandemic influenza virus strain nor the groups at highest risk for complications can necessarily be defined beforehand. Therefore, clinicians face significant challenges in: 1) quickly identifying and triaging cases, 2) containing the spread of infection, 3) beginning an efficient and comprehensive workup, 4) initiating antiviral and other supportive therapy, and 5) anticipating clinical complications.

**S5-II. OVERVIEW**

Supplement 5 provides clinical procedures for the initial screening, assessment, and management of patients with suspected novel influenza during the Interpandemic and Pandemic Alert Periods, and for patients with suspected pandemic influenza during the Pandemic Period. The Appendices include information on the clinical presentation and complications of seasonal influenza, the clinical features of infection due to avian influenza A (H5N1) virus and previous pandemic influenza viruses, and the management of patients with community-acquired pneumonia or secondary bacterial pneumonia during a pandemic. The guidance is current as of October 2005, and is subject to change as experience is gained. Updates will be provided, as needed, on the CDC website ([www.cdc.gov/flu/](http://www.cdc.gov/flu/)).

During the Interpandemic and Pandemic Alert Periods, early recognition of illness caused by a novel influenza A virus strain will rely on a combination of clinical and epidemiologic features. During the Pandemic Period (in a setting of high community

prevalence), diagnosis will likely be more clinically oriented because the likelihood will be high that any severe febrile respiratory illness is pandemic influenza. During periods in which no human infections with a novel influenza A virus strain have occurred anywhere in the world (Interpandemic Period: Phases 1, 2; see Box 1), or when sporadic cases of animal-to-human transmission or rare instances of limited human-to-human transmission of a novel influenza A virus strain have occurred in the world (Pandemic Alert Period: Phases 3, 4), the likelihood of novel influenza A virus infection is very low in a returned traveler from an affected area who has severe respiratory disease or influenza-like illness. Since human influenza A and B viruses circulate worldwide among humans year-round, the possibility of infection with human influenza viruses is much higher and should be considered. Once local person-to-person transmission of a novel influenza A virus strain has been confirmed (Pandemic Alert Period: Phase 5), the potential for novel influenza A virus infection will be higher in an ill person who has a strong epidemiologic link to the affected area (Box 1).

This supplement is designed to serve as a guide for clinicians, with the understanding that the management of influenza is based primarily on sound clinical judgment regarding the individual patient as well as an assessment of locally available resources, such as rapid diagnostics, antiviral drugs, and hospital beds. Early antiviral therapy shortens the duration of illness due to seasonal influenza and would be expected to have similar effects on illness due to novel or pandemic influenza viruses (see **Supplement 7: Antiviral Drug Distribution and Use**).<sup>1</sup>

Clinical management must also address supportive care and management of influenza-related complications.

Other supplements that cover topics of potential interest to clinicians:

Supplement 1. Pandemic Influenza Surveillance

Supplement 2. Laboratory Diagnostics

Supplement 3. Healthcare Planning

Supplement 4. Infection Control

Supplement 6. Vaccine Distribution and Use

Supplement 7. Antiviral Drug Distribution and Use

### **S5-III. CLINICAL GUIDELINES FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS**

During the Interpandemic and Pandemic Alert Periods, the primary goal of rapid detection is to quickly identify and contain cases of novel influenza. To limit the need to evaluate an overwhelming number of patients, the screening criteria should be specific, relying on a combination of clinical and epidemiologic features. Although febrile respiratory illnesses are one of the most common indications for medical evaluation, particularly during the winter, during the interpandemic and pandemic alert period, human cases of novel influenza are expected to be quite rare; laboratory diagnosis will most likely be sought for those with severe respiratory illness, such as pneumonia. The main features of detection and clinical management during the Interpandemic and Pandemic Alert Periods are outlined in Figure 1.

#### **A. Criteria for evaluation of patients with possible novel influenza**

The following criteria are based on the features of recent avian influenza A (H5N1) cases but are intended for use in evaluating suspected cases of infection with any novel influenza A virus strain. During the Pandemic Alert Period, human infections with novel influenza A viruses will be an uncommon cause of influenza-like illness; therefore, **both clinical and epidemiologic criteria should be met**. The criteria will be updated when needed as more data are collected.

<sup>1</sup> Information on HHS recommendations on the use of limited stocks of antiviral medications during a pandemic is provided in **Supplement 7**.

## 1. Clinical criteria

Any suspected cases of human infection with a novel influenza virus must first meet the criteria for influenza-like illness (ILI), defined as temperature of  $>38^{\circ}\text{C}$  plus either sore throat or cough. Since lower respiratory tract involvement might result in dyspnea (shortness of breath), dyspnea should be considered as an additional criterion. Therefore, the full clinical criteria are: **fever plus one of the following: sore throat, cough, or dyspnea.**

Although recent infections with novel influenza viruses have resulted in severe respiratory illness, the next pandemic influenza virus strain might present with a different clinical syndrome (see Appendix 1 and Appendix 2). In such a situation, the clinical criteria will be modified accordingly and posted at [www.cdc.gov/flu](http://www.cdc.gov/flu).

Given the large number of influenza-like illnesses that clinicians encounter during a typical flu season, **laboratory evaluation** for novel influenza A viruses during the Interpandemic and Pandemic Alert Periods is recommended only for:

- Hospitalized patients with severe ILI, including pneumonia, who meet the epidemiologic criteria (see below), *or*
- Non-hospitalized patients with ILI **and** with strong epidemiologic suspicion of novel influenza virus exposure (e.g., direct contact with ill poultry in an affected area, or close contact with a known or suspected human case of novel influenza.). (See Appendix 2, Supplement 2: Laboratory Diagnostics)
- Recommendations for the evaluation of patients with respiratory illnesses are provided in Box 2. Exceptions to the current clinical criteria are provided in Box 3.

## 2. Epidemiologic criteria

Epidemiologic criteria for evaluation of patients with possible novel influenza focus on the risk of exposure to a novel influenza virus with pandemic potential. Although the incubation period for seasonal influenza ranges from 1 to 4 days, the incubation periods for novel types of influenza are currently unknown and might be longer. Therefore, the maximum interval between potential exposure and symptom onset is set conservatively at 10 days.

**Exposure risks**—Exposure risks fall into two categories: travel and occupational.

### • Travel risks

Persons have a travel risk if they have: 1) recently visited or lived in an area affected by highly pathogenic avian influenza A outbreaks in domestic poultry or where a human case of novel influenza has been confirmed, *and either* 2) had direct contact with poultry, or 3) had close contact with a person with confirmed or suspected novel influenza. Updated listings of areas affected by avian influenza A (H5N1) and other current/recent novel strains are provided on the websites of the OIE ([http://www.oie.int/eng/en\\_index.htm](http://www.oie.int/eng/en_index.htm)), WHO ([www.who.int/en/](http://www.who.int/en/)), and CDC ([www.cdc.gov/flu/](http://www.cdc.gov/flu/)).

*Direct contact* with poultry is defined as: 1) touching birds (well-appearing, sick, or dead), or 2) touching poultry feces or surfaces contaminated with feces, or 3) consuming uncooked poultry products (including blood) in an affected area. *Close contact* with a person from an infected area with confirmed or suspected novel influenza is defined as being within 3 feet (1 meter) of that person during their illness.

Because specific testing for human infection with avian influenza A (H5N1) might not be locally available in an affected area, persons reporting close contact in an affected area with a person suffering from a severe, yet unexplained, respiratory illness should also be evaluated.

Clinicians should recognize that human influenza viruses circulate worldwide and year-round, including in countries with outbreaks of avian influenza A (H5N1) among poultry. Therefore, during the Interpandemic and Pandemic Alert Periods, human influenza virus infection can be a cause of ILI among returned travelers at any time of the year, including during the summer in the United States. This includes travelers returning from areas affected by poultry outbreaks of highly pathogenic avian influenza A (H5N1) in Asia. As of October 2005, such persons are currently more likely to have infection with human influenza viruses than with avian influenza A (H5N1) viruses.



- **Occupational risks**

Persons at occupational risk for infection with a novel strain of influenza include persons who work on farms or live poultry markets or who process or handle poultry infected with known or suspected avian influenza viruses, workers in laboratories that contain live animal or novel influenza viruses, and healthcare workers in direct contact with a suspected or confirmed novel influenza case.

Information on limiting occupational risk is provided on the Occupational Health and Safety Administration (OSHA) website at: [www.osha.gov/dsg/guidance/avian-flu.html](http://www.osha.gov/dsg/guidance/avian-flu.html).

During the Interpandemic and Pandemic Alert Periods, when there is no sustained human-to-human transmission of any novel influenza viruses, **direct contact with animals such as poultry in an affected area or close contact with a case of suspected or confirmed human novel influenza**—for any reason—is required for further evaluation. During the Pandemic Alert Period, Phases 3 and 4, the majority of human cases of novel influenza will result from avian-to-human transmission (see Box 1). Therefore, a history of direct contact with poultry (well-appearing, sick, or dead), consumption of uncooked poultry or poultry products, or direct exposure to environmental contamination with poultry feces in an affected area will be important to ascertain. During the Pandemic Alert Period, Phase 5, a history of close contact with an ill person suspected or confirmed to have novel influenza in an affected area will be even more important.

**Other avian influenza A viruses** — Although the epidemiologic criteria for novel influenza are based on recent human cases of avian influenza A (H5N1), they are intended for use in the evaluation of suspected cases of infection with any novel influenza A virus strain, including other avian influenza viruses. Other avian influenza A viruses that have caused human disease include the highly pathogenic viruses H7N7 and H7N3 and the low pathogenic viruses H9N2 and H7N2 (see Supplement 2, Box 3). Some of these human cases have occurred in Europe (Netherlands) and North America (Canada and the United States). Therefore, the same high-risk exposures defined above for avian influenza A (H5N1) also apply to other avian influenza A viruses. A strong epidemiologic link to an avian influenza outbreak in poultry—even in areas that have not experienced poultry outbreaks of avian influenza A (H5N1)—may raise the index of suspicion for human infection with avian influenza A viruses.

In the future, other animal hosts (in addition to poultry) or novel influenza A virus subtypes (in addition to H5N1) might become significantly associated with human disease. If such events occur, this guidance will be updated.

## **B. Initial management of patients who meet the criteria for novel influenza**

When a patient meets both the clinical and epidemiologic criteria for a suspected case of novel influenza, healthcare personnel should initiate the following activities:

- **Implement infection control precautions** for novel influenza, including Respiratory Hygiene/Cough Etiquette. Patients should be placed on Droplet Precautions for a minimum of 14 days, unless there is full resolution of illness or another etiology has been identified before that period has elapsed. Healthcare personnel should wear surgical or procedure masks on entering a patient's room, as per Droplet Precautions, as well as gloves and gowns, when indicated for Standard Precautions (Table). Patients should be admitted to a single-patient room, and patient movement and transport within the hospital should be limited to medically necessary purposes (see also Supplement 4).
- **Notify the local and state health departments.** Report each patient who meets the clinical and epidemiologic criteria for a suspected case of novel influenza to the state or local health department as quickly as possible to facilitate initiation of public health measures (see Supplement 1). Designate one person as a point of contact to update public health authorities on the patient's clinical status.
- **Obtain clinical specimens for novel influenza A virus testing and notify the local and state health departments to arrange testing.** Testing will likely be directed by public health authorities; current guidelines are provided in Supplement 2. Since the optimal specimens for detecting novel influenza A virus infections are currently unknown, if feasible, all of the following respiratory specimens should be collected for novel influenza A virus testing:

nasopharyngeal swab; nasal swab, wash, or aspirate; throat swab; and tracheal aspirate (for intubated patients). Store specimens at 4°C in viral transport media until transported or shipped for testing. Acute (within 7 days of illness onset) and convalescent serum specimens (2–3 weeks after the acute specimen and at least 3 weeks after illness onset) should be obtained and refrigerated at 4°C or frozen at minus 20–80°C. Serological testing for novel influenza virus infection can be performed only at CDC.

Clinicians should immediately notify their local health departments of their intention to ship clinical specimens from suspected cases of human infection with avian influenza, to ensure that the specimens are handled under proper biocontainment conditions (see Supplement 2).

**Novel influenza can be confirmed by RT-PCR or virus isolation from tissue cell culture with subtyping.** RT-PCR for testing of novel influenza viruses cannot be performed by a hospital laboratory and is available only at state public health laboratories and CDC. **Viral culture of specimens from suspected novel influenza cases should be attempted only in laboratories that meet the biocontainment conditions for BSL-3 with enhancements or higher.**

**Rapid influenza diagnostic tests and immunofluorescence** (indirect fluorescent antibody staining [IFA] or direct fluorescent antibody staining [DFA]) may be used to detect seasonal influenza, but **should not be used to confirm or exclude novel influenza during the Pandemic Alert Period.** Rapid influenza tests have relatively low sensitivity for detecting seasonal influenza,<sup>2</sup> and their ability to detect novel influenza subtypes is unknown. The sensitivity of rapid diagnostic tests will likely be higher in specimens collected within two days of illness onset, in children, and when tested in clinical laboratories that perform a high volume of testing. Such tests can identify influenza A viruses but cannot distinguish between human infection with seasonal and novel influenza A viruses. A negative rapid influenza test result does not necessarily exclude human infection with either seasonal or novel influenza A viruses. A positive rapid influenza test result could be a false positive or represent infection with either seasonal or novel influenza A viruses. Therefore, both negative and positive rapid influenza test and immunofluorescence results should be interpreted with caution, and RT-PCR testing for influenza viruses should be performed. Further information on rapid diagnostic testing is provided in Supplement 2.

Acute and convalescent serum samples and other available clinical specimens (respiratory, blood, and stool) should be saved and refrigerated or frozen for additional testing until a specific diagnosis is made.

- **Evaluate alternative diagnoses.** An alternative diagnosis should be based only on laboratory tests with high positive-predictive value (e.g., blood culture, viral culture, PCR, *Legionella* urinary antigen, pleural fluid culture, transthoracic aspirate culture). If an alternate etiology is identified, the possibility of co-infection with a novel influenza virus may still be considered if there is a strong epidemiologic link to exposure to novel influenza.
- **Decide on inpatient or outpatient management.** The decision to hospitalize a suspected novel influenza case will be based on the physician's clinical assessment and assessment of risk and whether adequate precautions can be taken at home to prevent the potential spread of infection. Patients cared for at home should be separated from other household members as much as possible. All household members should carefully follow recommendations for hand hygiene, and tissues used by the ill patient should be placed in a bag and disposed with other household waste (Box 4). Although no studies have assessed the use of masks at home to decrease the spread of infection, use of surgical or procedure masks by the patient and/or caregiver during interactions may be of benefit. Separation of eating utensils for use by a patient with influenza is not necessary, as long as they are washed with warm water and soap (Box 4).
- **Initiate antiviral treatment** as soon as possible, even if laboratory results are not yet available. Clinical trials have shown that these drugs can decrease the illness due to seasonal influenza duration by several days when they are initiated within 48 hours of illness onset. The clinical effectiveness of antiviral drugs for treatment of novel influenza is unknown, but it is likely that the earlier treatment is initiated, the greater the likelihood of benefit. During the

<sup>2</sup> Uyeki TM. Influenza diagnosis and treatment in children: a review of studies on clinically useful tests and antiviral treatment for influenza. *Pediatr Infect Dis J*. 2003 Feb;22(2):164–77.

Pandemic Alert Period, available virus isolates from any case of novel influenza will be tested for resistance to the currently licensed antiviral medications. See **Supplement 7** for current antiviral information and treatment strategies.

- **Assist public health officials with the identification of potentially exposed contacts.** After consulting with state and local public health officials, clinicians might be asked to help identify persons exposed to the suspected novel influenza case-patient (particularly healthcare workers). In general, persons in close contact with the case-patient at any time beginning one day before the onset of illness are considered at risk. Close contacts might include household and social contacts, family members, workplace or school contacts, fellow travelers, and/or healthcare providers (see **Supplement 8** and **Supplement 9**).

### **C. Management of patients who test positive for novel influenza**

If a patient is confirmed to have an infection with a novel influenza virus, healthcare personnel should continue antiviral treatment and all isolation and infection control precautions, and isolate patients with novel influenza from seasonal influenza patients. In addition to prior vaccination against seasonal influenza, such measures may decrease the risk of co-infection and viral genetic reassortment.

### **D. Management of patients who test positive for seasonal influenza**

Many suspected novel influenza cases may be found to have seasonal human influenza, particularly during the winter season. It should be recognized that human influenza viruses circulate among people worldwide, including in affected areas with poultry outbreaks of avian influenza A viruses during non-seasonal influenza activity in the United States. For patients with confirmed seasonal influenza, maintain Standard and Droplet Precautions, and continue antiviral treatment for a full treatment course (e.g., 5 days).

### **E. Management of patients who test negative for novel influenza**

The sensitivity of the currently available tests for detecting novel influenza viruses in clinical specimens has not been thoroughly evaluated with a full range of specimen types. Consequently, false-negative test results may occur. Therefore, if test results are negative but the clinical and epidemiologic suspicion remains high, continuing antiviral treatment and isolation procedures should be considered. Test results might be negative for influenza viruses for several reasons. Some patients might have an alternate etiology to explain their illness. The general work-up for febrile respiratory illnesses described below should evaluate the most common alternate causes. A certain number of truly infected cases might also test falsely negative, due to specimen collection conditions, to viral shedding that is not detectable, or to sensitivity of the test. Interpretation of negative testing results should be tailored to the individual patient in consultation with hospital infection control and infectious disease specialists, as well as the state or local health department and CDC. In hospitalized patients who test negative for novel influenza but have no alternate diagnosis established, novel-influenza-directed management should be continued if clinical suspicion is high and there is a strong epidemiologic link to exposure to novel influenza. When influenza tests are negative and an alternative diagnosis is established, isolation precautions and antiviral drug therapy for novel influenza may be discontinued based on clinician's assessment, particularly in the absence of a strong epidemiologic link, if the alternative diagnosis is made using a test with a high positive-predictive value, and if the clinical manifestations are explained by the alternative diagnosis.

## **S5-IV. CLINICAL GUIDELINES FOR THE PANDEMIC PERIOD**

During the Pandemic Period, the primary goal of rapid detection is to appropriately identify and triage cases of pandemic influenza. During this period, outpatient clinics and emergency departments might be overwhelmed with suspected cases, restricting the time and laboratory resources available for evaluation. In addition, if the pandemic influenza virus exhibits transmission characteristics similar to those of seasonal influenza viruses, illnesses will likely spread throughout the community too rapidly to allow the identification of obvious exposures or contacts. Evaluation will therefore focus predominantly on clinical and basic laboratory findings, with less emphasis on laboratory diagnostic testing (which may be in

short supply) and epidemiologic criteria. Nevertheless, clinicians in communities without pandemic influenza activity might consider asking patients about recent travel from a community with pandemic influenza activity or close contact with a suspected or confirmed pandemic influenza case. The main features of clinical management during the Pandemic Period are outlined in Figure 2.

## A. Criteria for evaluation of patients with possible pandemic influenza

### 1. Clinical criteria

Suspected cases of pandemic influenza virus infection should meet the criteria for ILI: temperature of  $>38^{\circ}\text{C}$  plus either sore throat or cough. Since lower respiratory tract involvement might result in dyspnea (shortness of breath), dyspnea should be considered as an additional criterion. Therefore, the full clinical criteria are: **fever plus one of the following: sore throat, cough, or dyspnea**. Although past influenza pandemics have most frequently resulted in respiratory illness, the next pandemic influenza virus strain might present with a different clinical syndrome (see Appendix 1 and Appendix 2). During a pandemic, updates on other clinical presentations will be provided at: [www.pandemicflu.gov](http://www.pandemicflu.gov) and [www.cdc.gov/flu/](http://www.cdc.gov/flu/).

Recommendations for general evaluation of patients with influenza-like illness are provided in Box 2. Exceptions to the clinical criteria are provided in Box 3.

### 2. Epidemiologic criteria

During the Pandemic Period, an exposure history will be marginally useful for clinical management when disease is widespread in a community. In addition, there will be a relatively high likelihood that any case of ILI during that time period will be pandemic influenza. Once pandemic influenza has arrived in a particular locality, clinical criteria will be sufficient for classifying the patient as a suspected pandemic influenza case.

## B. Initial management of patients who meet the criteria for pandemic influenza

When a patient meets the criteria for a suspected case of pandemic influenza, healthcare personnel should initiate the following activities:

- **Follow local and state health department recommendations on reporting** for patients who meet the criteria for pandemic influenza. See **Supplement 1** for guidance on case reporting during the Pandemic Period.
- **If the patient is hospitalized, implement infection control precautions for pandemic influenza**, including Respiratory Hygiene/Cough Etiquette (see Table and **Supplement 4**). Place the patient on Droplet Precautions for a minimum of 5 days from the onset of symptoms. Healthcare personnel should wear surgical or procedure masks on entering a patient's room, as per Droplet Precautions, as well as gloves and gowns when indicated, as per Standard Precautions (Table). Once a pandemic is underway, hospital admission of patients should be limited to those with severe complications who cannot be cared for outside the hospital setting. Patients should be admitted to either a single-patient room or an area designated for cohorting of patients with influenza. Patient movement and transport outside the isolation area should be limited to medically necessary purposes (see Table).
- **Obtain clinical specimens** for general evaluation, as clinically indicated (see Box 2). Once pandemic influenza has arrived in a community, influenza testing will likely not be needed for most patients. Laboratory testing in conjunction with health departments will likely be performed in a subset of pandemic influenza cases, however, as part of ongoing virologic surveillance to monitor the antigenic evolution of the strains for vaccine strain selection purposes (see **Supplement 1**). At the beginning or end of a pandemic outbreak in a community, diagnostic testing might aid cohorting decisions, but may be optional in the setting of high local prevalence. Influenza diagnostic testing should be considered before initiating treatment with antivirals (see **Supplement 7**). Guidelines for pandemic influenza virus testing are provided in **Supplement 2**.

As with seasonal influenza, RT-PCR and virus isolation from tissue culture will be the most accurate methods for diagnosing pandemic influenza. Generally, specimens should include combined nasopharyngeal aspirates or nasal swabs, and throat swabs, stored at 4°C in viral transport media. During the Pandemic Period, BSL-2 conditions should be sufficient for viral culture of clinical specimens from suspected pandemic influenza patients.

Rapid diagnostic tests for influenza and immunofluorescence may be helpful for initial clinical management, including cohorting and treatment (see above). However, rapid influenza tests have relatively low sensitivity for detecting seasonal influenza, and their ability to detect pandemic influenza viruses is unknown. The sensitivity of rapid diagnostic tests will likely be higher in specimens collected within two days of illness onset, in children, and when tested at clinical laboratories that perform a high volume of testing. Because during a pandemic a negative rapid test may be a false negative, test results need to be interpreted within the overall clinical context. For example, it may not be optimal to withhold antiviral treatment from a seriously ill high risk patient on the basis of a negative test; however, in a setting of limited antiviral drug availability, treatment decisions in less high risk situations could be based on test results. The risk of a false-negative test also must be taken into account in making cohorting decisions. Rapid diagnostic testing should not preclude more reliable testing, if available. Further information on rapid diagnostic testing can be found in **Supplement 2**.

- **Decide on inpatient or outpatient management.** The decision to hospitalize a suspected pandemic influenza case will be based on the physician's clinical assessment of the patient as well as the availability of hospital beds and personnel. Guidelines on cohorting and infection control for admitted patients can be found in **Supplement 3** and **Supplement 4**.

An unstable patient will be considered a high priority for admission, but patients with high-risk conditions (see Appendix 1) might also warrant special attention, such as observation or close follow-up, even if disease is mild. On the other hand, home management with follow-up might be appropriate for well-appearing young children with fever alone. See **Supplement 7** for inpatient and outpatient treatment strategies.

Patients cared for at home should be separated from other household members as much as possible. All household members should carefully follow recommendations for hand hygiene, and tissues used by the ill patient should be placed in a bag and disposed with other household waste (Box 4). Infection within the household may be minimized if a primary caregiver is designated; ideally, someone who does not have an underlying condition that places them at increased risk of severe influenza disease. Although no studies have assessed the use of masks at home to decrease the spread of infection, using a surgical or procedure mask by the patient or caregiver during interactions may be of benefit. Separation of eating utensils for use by a patient with influenza is not necessary, as long as they are washed with warm water and soap (Box 4).

## C. Clinical management of pandemic influenza patients

See **Supplement 7** for current antiviral information and treatment strategies.<sup>3</sup> In addition to use of antivirals, clinical management of severe influenza should address supportive care and the rapid identification and treatment of secondary complications. During the Pandemic Period, CDC may request virus isolates from persons who fail treatment or antiviral prophylaxis, as these strains may more likely be drug resistant. In addition, randomly collected isolates will be tested for resistance to establish nationwide rates (see **Supplement 1**).

Children aged <18 years with suspected or confirmed pandemic influenza should not be treated with aspirin or other salicylate-containing products because of an increased risk of Reye syndrome (characterized by acute encephalopathy and liver failure) in this age group.

<sup>3</sup> Ribavirin and immunomodulatory therapies, such as steroids, are not approved by the FDA for treatment of severe influenza of any type and are purely investigational at this time. These agents frequently have severe adverse effects, such as bone marrow and hepatic toxicity, while the benefits of these therapies are unknown.

The major clinical presentations and complications related to seasonal human influenza occur more commonly in persons with certain underlying medical conditions, such as chronic respiratory or cardiovascular disease and extremes of age, and are described in Appendix 1. Limited data are available on risk factors and complications related to infection with novel influenza viruses, and these may change as individual strains evolve. A summary of the clinical presentations and complications associated with recent influenza A (H5N1) viruses is included in Appendix 2. In particular, post-influenza community-acquired pneumonia will likely be a commonly encountered complication, and clinicians will need to be aware of recommended methods for diagnosis and treatment. Guidance on the management of influenza-related pneumonia is presented in Appendix 3.



## **BOX 1. RISK OF NOVEL INFLUENZA IN PERSONS WITH SEVERE RESPIRATORY DISEASE OR INFLUENZA-LIKE ILLNESS DURING THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS**

Clinicians should recognize that human influenza A and B viruses and other respiratory viruses circulate year-round among people throughout the world, including in countries affected by outbreaks of avian influenza A viruses in poultry. Seasonal human influenza A and B community outbreaks occur in temperate climates of the northern and southern hemisphere, and human influenza activity may occur year-round in subtropical and tropical regions. Outbreaks of human influenza can occur among travelers during any time of the year, including periods of low influenza activity in the United States (e.g., summer).

### **Phases 1, 2: Interpandemic Period**

A novel influenza A virus has been detected in animals but not in humans. During these phases, the risk of human infection with a novel influenza A virus strain is extremely low. The risk of human infection with human influenza viruses or other viruses is much higher in persons living in or traveling to affected areas.

### **Phases 3, 4: Pandemic Alert Period**

A novel influenza A virus has been detected in humans through sporadic animal-to-human transmission in an affected area (e.g., direct contact with infected poultry), and few cases of limited, local human-to-human transmission have occurred (small clusters of cases). During these phases, the risk of human infection with a novel influenza A virus strain is very low. The risk of human infection with human influenza viruses or other viruses is much higher in persons living in or traveling to affected areas.

### **Phase 5: Pandemic Alert Period**

A novel influenza A virus has been detected in humans in larger clusters in an affected area, suggesting that the virus is becoming better adapted to spread among people. During this period, the risk of human infection with a novel influenza A virus strain is higher, depending on specific exposures, in persons living in or traveling to affected areas. Human infection with human influenza viruses or other viruses will occur and should still be considered.



## BOX 2. CLINICAL EVALUATION OF PATIENTS WITH INFLUENZA-LIKE ILLNESS DURING THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS

- Patients who require hospitalization for an influenza-like illness for which a definitive alternative diagnosis is not immediately apparent\* should be questioned about: 1) travel to an area affected by avian influenza A virus outbreaks in poultry, 2) direct contact with poultry, 3) close contact with persons with suspected or confirmed novel influenza, or 4) occupational exposure to novel influenza viruses (such as through agricultural, health care, or laboratory activities).
- Patients may be screened on admission for recent seasonal influenza vaccination and pneumococcal vaccination. Those without a history of immunization should receive these vaccines before discharge, if indicated.
- Patients meeting the epidemiologic criteria for possible infection with a novel strain of influenza should undergo a routine diagnostic work-up, guided by clinical indications. Appropriate personal protective equipment should be used when evaluating patients with suspected novel influenza, including during collection of specimens.\*\*
- Diagnostic testing for a novel influenza A virus should be initiated as follows:
  - Collect all of the following specimens: nasopharyngeal swab, nasal swab, wash, or aspirate, throat swab, and tracheal aspirate (if intubated), and place into viral transport media and refrigerate at 4° C until specimens can be transported for testing.
  - Immediately contact the local and state health departments to report the suspected case and to arrange novel influenza testing by RT-PCR.

RT-PCR testing is not available in hospital laboratories and must be performed at a qualified laboratory such as a state health department laboratory or the CDC Influenza Laboratory. **Viral culture should be performed only at biosafety level 3 [BSL-3] with enhancements (see Supplement 2).**

- Depending on the clinical presentation and the patient's underlying health status, other initial diagnostic testing might include:
  - Pulse oximetry
  - Chest radiograph
  - Complete blood count (CBC) with differential
  - Blood cultures
  - Sputum (in adults), tracheal aspirate, and pleural effusion aspirate (if an effusion is present) Gram stain and culture
  - Antibiotic susceptibility testing (encouraged for all bacterial isolates)
  - Multivalent immunofluorescent antibody testing or PCR of nasopharyngeal aspirates or swabs for common viral respiratory pathogens, such as influenza A and B, adenovirus, parainfluenza viruses, and respiratory syncytial virus, particularly in children
  - In adults with radiographic evidence of pneumonia, *Legionella* and pneumococcal urinary antigen testing
  - If clinicians have access to rapid and reliable testing (e.g., PCR) for *M. pneumoniae* and *C. pneumoniae*, adults and children <5 yrs with radiographic pneumonia should be tested.
  - Comprehensive serum chemistry panel, if metabolic derangement or other end-organ involvement, such as liver or renal failure, is suspected

\*Further evaluation and diagnostic testing should also be considered for outpatients with strong epidemiologic risk factors and mild or moderate illness (see Box 3).

\*\*Healthcare personnel should wear surgical or procedure masks on entering a patient's room (Droplet Precautions), as well as gloves and gowns, when indicated (Standard Precautions) (see Table and Supplement 4).

### BOX 3. SPECIAL SITUATIONS AND EXCEPTIONS TO THE CLINICAL CRITERIA

**Persons with a high risk of exposure**—For persons with a high risk of exposure to a novel influenza virus (e.g., poultry worker from an affected area,\* caregiver of a patient with laboratory-confirmed novel influenza, employee in a laboratory that works with live novel influenza viruses), epidemiologic evidence might be enough to initiate further measures, even if clinical criteria are not fully met. In these persons, early signs and symptoms—such as rhinorrhea, conjunctivitis, chills, rigors, myalgia, headache, and diarrhea—in addition to cough or sore throat, may be used to fulfill the clinical criteria for evaluation.

**High-risk groups with atypical symptoms**—Young children, elderly patients, patients in long-term care facilities, and persons with underlying chronic illnesses might not have typical influenza-like symptoms, such as fever. When such patients have a strong epidemiologic risk factor, novel influenza should be considered with almost any change in health status, even in the absence of typical clinical features. Conjunctivitis has been reported in patients with influenza A (H7N7) and (H7N3) infections. In young children, gastrointestinal manifestations such as vomiting and diarrhea might be present. Infants may present with fever or apnea alone, without other respiratory symptoms, and should be evaluated if there is an otherwise increased suspicion of novel influenza.

---

\*Updated lists of affected areas are provided at the websites of the OIE ([http://www.oie.int/eng/en\\_index.htm](http://www.oie.int/eng/en_index.htm)), WHO ([www.who.int/en/](http://www.who.int/en/)), and CDC ([www.cdc.gov/flu/](http://www.cdc.gov/flu/)).

## **BOX 4. HOME CARE INFECTION CONTROL GUIDANCE FOR PANDEMIC INFLUENZA PATIENTS AND HOUSEHOLD MEMBERS**

Most patients with pandemic influenza will be able to remain at home during the course of their illness and can be cared for by family members or others who live in the household. Anyone who has been in the household with an influenza patient during the incubation period is at risk for developing influenza. A key objective in this setting is to limit transmission of pandemic influenza within and outside the home.

### **Management of influenza patients in the home**

- Physically separate the patient with influenza from non-ill persons living in the home as much as possible.
- Patients should not leave the home during the period when they are most likely to be infectious to others (i.e., 5 days after onset of symptoms). When movement outside the home is necessary (e.g., for medical care), the patient should follow respiratory hygiene/cough etiquette (i.e., cover the mouth and nose when coughing and sneezing) and should wear a mask.

### **Management of other persons in the home**

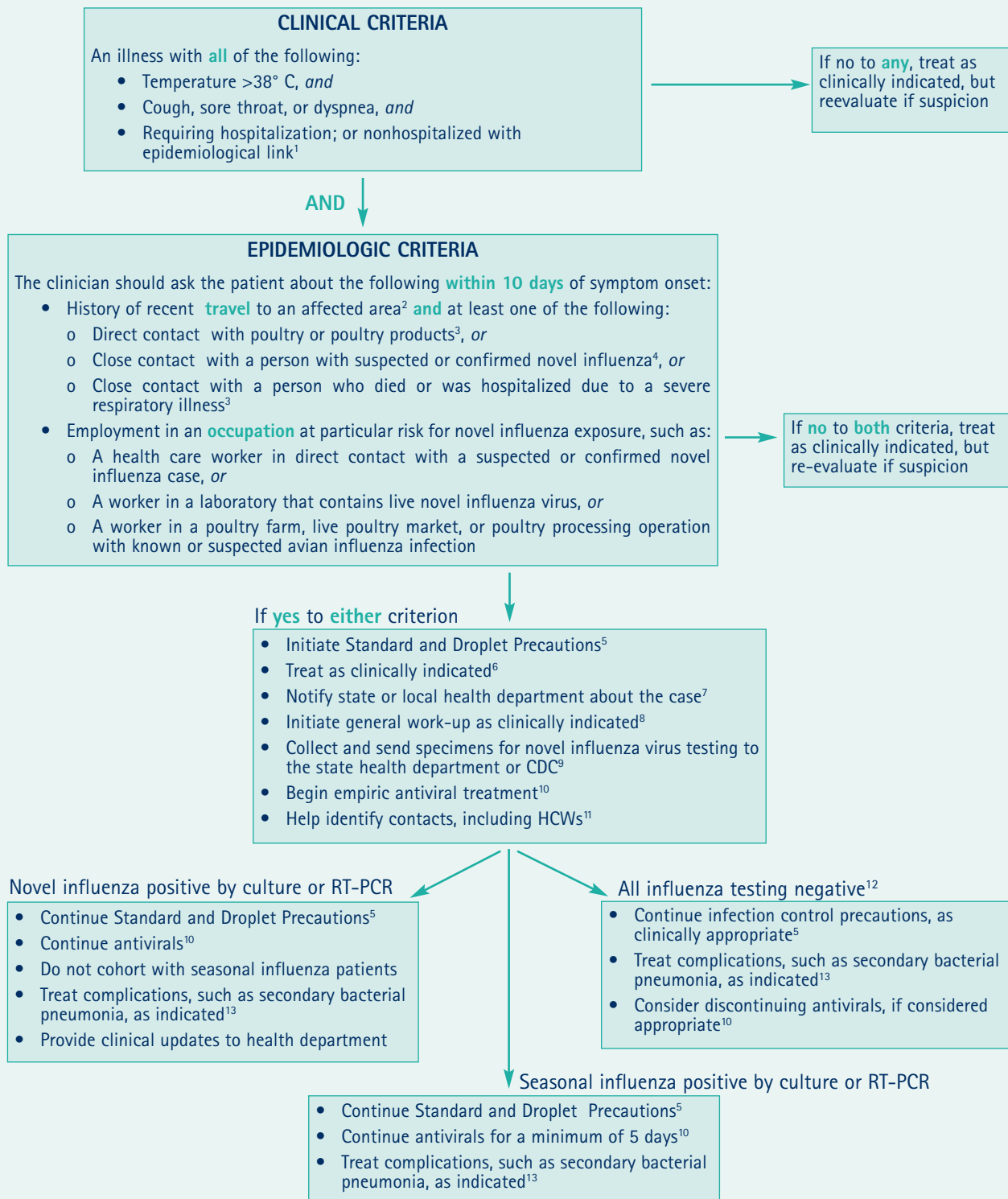
- Persons who have not been exposed to pandemic influenza and who are not essential for patient care or support should not enter the home while persons are still having a fever due to pandemic influenza.
- If unexposed persons must enter the home, they should avoid close contact with the patient.
- Persons living in the home with the patient with pandemic influenza should limit contact with the patient to the extent possible; consider designating one person as the primary care provider.
- Household members should be vigilant for the development of influenza symptoms. Consult with healthcare providers to determine whether a pandemic influenza vaccine, if available, or antiviral prophylaxis should be considered.

### **Infection control measures in the home**

- All persons in the household should carefully follow recommendations for hand hygiene (i.e., hand washing with soap and water or use of an alcohol-based hand rub) after contact with an influenza patient or the environment in which they are receiving care.
- Although no studies have assessed the use of masks at home to decrease the spread of infection, using a surgical or procedure mask by the patient or caregiver during interactions may be beneficial.
- Soiled dishes and eating utensils should be washed either in a dishwasher or by hand with warm water and soap. Separation of eating utensils for use by a patient with influenza is not necessary.
- Laundry may be washed in a standard washing machine with warm or cold water and detergent. It is not necessary to separate soiled linen and laundry used by a patient with influenza from other household laundry. Care should be used when handling soiled laundry (i.e., avoid "hugging" the laundry) to avoid self-contamination. Hand hygiene should be performed after handling soiled laundry.
- Tissues used by the ill patient should be placed in a bag and disposed of with other household waste. Consider placing a bag for this purpose at the bedside.
- Environmental surfaces in the home should be cleaned using normal procedures.

## FIGURE 1. CASE DETECTION AND CLINICAL MANAGEMENT DURING THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS

**Situation:** No human cases of novel influenza are present in the community. Human cases might be present in another country or another region of the United States.

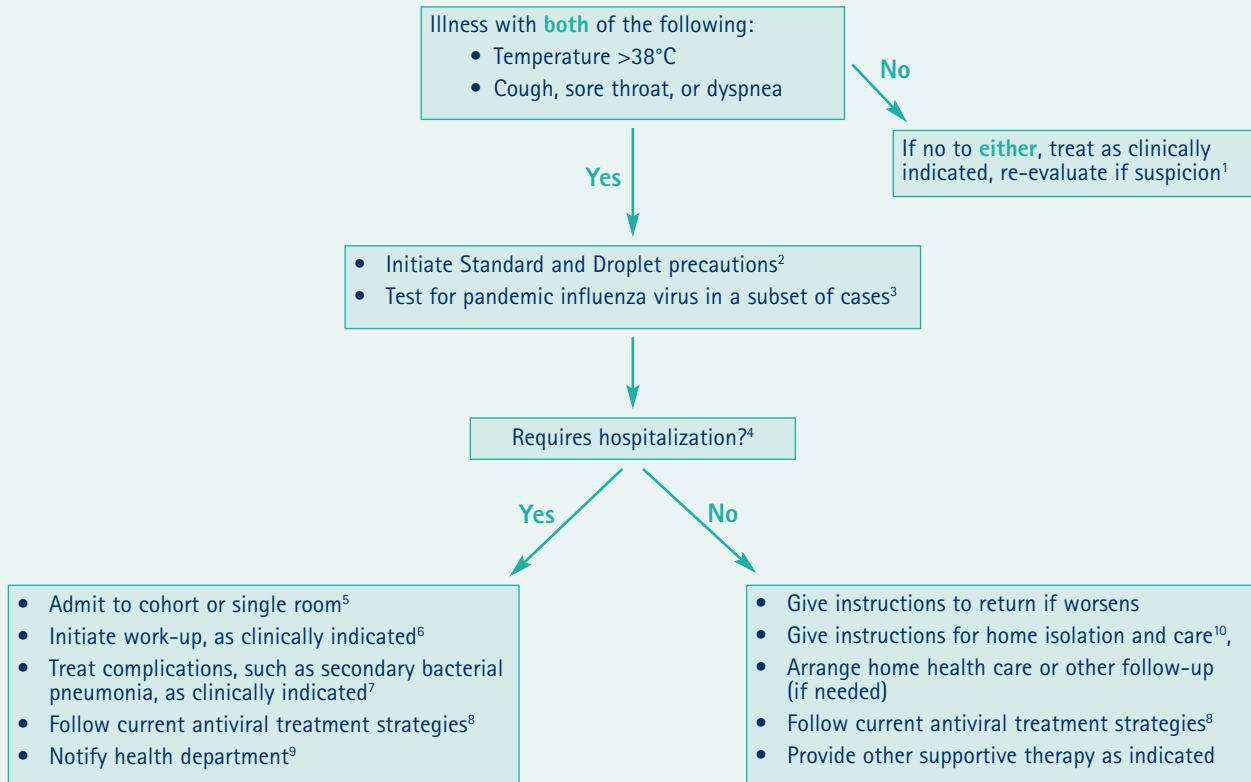


### Footnotes to Figure 1:

1. Further evaluation and diagnostic testing should also be considered for outpatients with strong epidemiologic risk factors and mild or moderate illness. (See Box 2).
2. Updated information on areas where novel influenza virus transmission is suspected or documented is available on the CDC website at [www.cdc.gov/travel/other/avian\\_flu\\_ah5n1\\_031605.htm](http://www.cdc.gov/travel/other/avian_flu_ah5n1_031605.htm) and on the WHO website at [www.who.int/en/](http://www.who.int/en/).
3. For persons who live in or visit affected areas, close contact includes touching live poultry (well-appearing, sick or dead) or touching or consuming uncooked poultry products, including blood. For animal or market workers, it includes touching surfaces contaminated with bird feces. In recent years, most instances of human infection with a novel influenza A virus having pandemic potential, including influenza A (H5N1), are thought to have occurred through direct transmission from domestic poultry. A small number of cases are also thought to have occurred through limited person-to-person transmission or consumption of uncooked poultry products. Transmission of novel influenza viruses from other infected animal populations or by contact with fecally contaminated surfaces remains a possibility. These guidelines will be updated as needed if alternate sources of novel influenza viruses are suspected or confirmed.
4. Close contact includes direct physical contact, or approach within 3 feet (1 meter) of a person with suspected or confirmed novel influenza.
5. Standard and Droplet Precautions should be used when caring for patients with novel influenza or seasonal influenza (Table and **Supplement 4**). Information on infection precautions that should be implemented for all respiratory illnesses (i.e., Respiratory Hygiene/Cough Etiquette) is provided at: [www.cdc.gov/flu/professionals/infectioncontrol/resphgiene.htm](http://www.cdc.gov/flu/professionals/infectioncontrol/resphgiene.htm)
6. Hospitalization should be based on all clinical factors, including the potential for infectiousness and the ability to practice adequate infection control. If hospitalization is not clinically warranted, and treatment and infection control is feasible in the home, the patient may be managed as an outpatient. The patient and his or her household should be provided with information on infection control procedures to follow at home (Box 3). The patient and close contacts should be monitored for illness by local public health department staff.
7. Guidance on how to report suspected cases of novel influenza is provided in **Supplement 1**.
8. The general work-up should be guided by clinical indications. Depending on the clinical presentation and the patient's underlying health status, initial diagnostic testing might include:
  - Pulse oximetry
  - Chest radiograph
  - Complete blood count (CBC) with differential
  - Blood cultures
  - Sputum (in adults), tracheal aspirate, pleural effusion aspirate (if pleural effusion is present) Gram stain and culture
  - Antibiotic susceptibility testing (encouraged for all bacterial isolates)
  - Multivalent immunofluorescent antibody testing or PCR of nasopharyngeal aspirates or swabs for common viral respiratory pathogens, such as influenza A and B, adenovirus, parainfluenza viruses, and respiratory syncytial virus, particularly in children
  - In adults with radiographic evidence of pneumonia, *Legionella* and pneumococcal urinary antigen testing
  - If clinicians have access to rapid and reliable testing (e.g., PCR) for *M. pneumoniae* and *C. pneumoniae*, adults and children <5 yrs with radiographic pneumonia should be tested.
  - Comprehensive serum chemistry panel, if metabolic derangement or other end-organ involvement, such as liver or renal failure, is suspected

See Box 2 for additional details.
9. Guidelines for novel influenza virus testing can be found in **Supplement 2**. All of the following respiratory specimens should be collected for novel influenza A virus testing: nasopharyngeal swab; nasal swab, wash, or aspirate; throat swab; and tracheal aspirate (for intubated patients), stored at 4°C in viral transport media; and acute and convalescent serum samples.
10. Strategies for the use of antiviral drugs are provided in **Supplement 7**.
11. Guidelines for the management of contacts in a healthcare setting are provided in **Supplement 3**.
12. Given the unknown sensitivity of tests for novel influenza viruses, interpretation of negative results should be tailored to the individual patient in consultation with the local health department. Novel influenza directed management may need to be continued, depending on the strength of clinical and epidemiologic suspicion. Antiviral therapy and isolation precautions for novel influenza may be discontinued on the basis of an alternative diagnosis. The following criteria may be considered for this evaluation:
  - Absence of strong epidemiologic link to known cases of novel influenza
  - Alternative diagnosis confirmed using a test with a high positive-predictive value
  - Clinical manifestations explained by the alternative diagnosis
13. Guidance on the evaluation and treatment of suspected post-influenza community-associated pneumonia is provided in Appendix 3.

## FIGURE 2. CASE DETECTION AND CLINICAL MANAGEMENT DURING THE PANDEMIC PERIOD



**Situation:** Pandemic influenza viruses are circulating in the community.

## Footnotes to Figure 2:

1. Antiviral therapy and isolation precautions for pandemic influenza should be discontinued on the basis of an alternative diagnosis only when both the following criteria are met:
    - Alternative diagnosis confirmed using a test with a high positive-predictive value, and
    - Clinical manifestations entirely explained by the alternative diagnosis
  2. Standard and Droplet Precautions should be used when caring for patients with novel influenza or seasonal influenza (Table and Supplement 4). Information on infection precautions that should be implemented for all respiratory illnesses (i.e., Respiratory Hygiene/Cough Etiquette) is provided at: [www.cdc.gov/flu/professionals/infectioncontrol/resphygiene.htm](http://www.cdc.gov/flu/professionals/infectioncontrol/resphygiene.htm)
  3. Guidance on laboratory testing during the Pandemic Period can be found in Supplement 2. Generally, specimens should include respiratory samples (e.g., nasopharyngeal wash/aspirate; nasopharyngeal, nasal or oropharyngeal swabs, or tracheal aspirates) stored at 4°C in viral transport media.
- Routine laboratory confirmation of clinical diagnoses will be unnecessary as pandemic activity becomes widespread in a community. CDC will continue to work with state health laboratories to conduct virologic surveillance to monitor antigenic changes and antiviral resistance in the pandemic virus strains throughout the Pandemic Period.
4. The decision to hospitalize should be based on a clinical assessment of the patient and the availability of hospital beds and personnel.
  5. Guidelines on cohorting can be found in Supplement 4. Laboratory confirmation of influenza infection is recommended when possible before cohorting patients.
  6. The general work-up should be guided by clinical indications. Depending on the clinical presentation and the patient's underlying health status, initial diagnostic testing might include:
    - Pulse oximetry
    - Chest radiograph
    - Complete blood count (CBC) with differential
    - Blood cultures
    - Sputum (in adults) or tracheal aspirate Gram stain and culture
    - Antibiotic susceptibility testing (encouraged for all bacterial isolates)
    - Multivalent immunofluorescent antibody testing of nasopharyngeal aspirates or swabs for common viral respiratory pathogens, such as influenza A and B, adenovirus, parainfluenza viruses, and respiratory syncytial virus, particularly in children
    - In adults with radiographic evidence of pneumonia, *Legionella* and pneumococcal urinary antigen testing
    - If clinicians have access to rapid and reliable testing (e.g., PCR) for *M. pneumoniae* and *C. pneumoniae*, adults and children <5 yrs with radiographic pneumonia should be tested.
    - Comprehensive serum chemistry panel, if metabolic derangement or other end-organ involvement, such as liver or renal failure, is suspected

See Box 2 for additional details.
  7. Guidance on the evaluation and treatment of community acquired pneumonia and suspected post-influenza community-acquired bacterial pneumonia are provided in Appendix 3.
  8. Strategies for the use of antiviral drugs are provided in Supplement 7.
  9. Guidance on the reporting of pandemic influenza cases is provided in Supplement 1.
  10. Patients with mild disease should be provided with standardized instructions on home management of fever and dehydration, pain relief, and recognition of deterioration in status. Patients should also receive information on infection control measures to follow at home (Box 4). Patients cared for at home should be separated from other household members as much as possible. All household members should carefully follow recommendations for hand hygiene, and tissues used by the ill patient should be placed in a bag and disposed of with other household waste. Infection within the household may be minimized if a primary caregiver is designated; ideally, someone who does not have an underlying condition that places them at increased risk of severe influenza disease. Although no studies have assessed the use of masks at home to decrease the spread of infection, using a surgical or procedure mask by the patient or caregiver during interactions may be beneficial. Separation of eating utensils for use by a patient with influenza is not necessary, as long as they are washed with warm water and soap. Additional information on measures to limit the spread of pandemic influenza in the home and community can be found in Supplement 4 and Supplement 8.



**TABLE 1. PANDEMIC INFLUENZA INFECTION CONTROL GUIDANCE FOR HEALTHCARE PROVIDERS**

| COMPONENT                                                                                                                                                                                               | RECOMMENDATIONS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| STANDARD PRECAUTIONS                                                                                                                                                                                    | See <a href="http://www.cdc.gov/hicidod/hip/ISOLAT/std_prec_excerpt.htm">www.cdc.gov/hicidod/hip/ISOLAT/std_prec_excerpt.htm</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Hand hygiene                                                                                                                                                                                            | Perform hand hygiene after touching blood, body fluids, secretions, excretions, and contaminated items; after removing gloves; between patient contacts. Hand hygiene includes both handwashing with either plain or antimicrobial soap and water and use of alcohol-based products (gels, rinses, foams) that contain an emollient and do not require the use of water. If hands are visibly soiled or contaminated with respiratory secretions, they should be washed with soap (either non-antimicrobial or antimicrobial) and water. In the absence of visible soiling of hands, approved alcohol-based products for hand disinfection are preferred over antimicrobial or plain soap and water because of their superior microbiocidal activity, reduced drying of the skin, and convenience. |
| Personal protective equipment (PPE) <ul style="list-style-type: none"> <li>Gloves</li> <li>Gown</li> <li>Face/eye protection (e.g., surgical or procedure mask and goggles or a face shield)</li> </ul> | <ul style="list-style-type: none"> <li>For touching blood, body fluids, secretions, excretions, and contaminated items; for touching mucous membranes and nonintact skin</li> <li>During procedures and patient-care activities when contact of clothing/exposed skin with blood/body fluids, secretions, and excretions is anticipated</li> <li>During procedures and patient care activities likely to generate splash or spray of blood, body fluids, secretions, excretions</li> </ul>                                                                                                                                                                                                                                                                                                         |
| Safe work practices                                                                                                                                                                                     | Avoid touching eyes, nose, mouth, or exposed skin with contaminated hands (gloved or ungloved); avoid touching surfaces with contaminated gloves and other PPE that are not directly related to patient care (e.g., door knobs, keys, light switches).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Patient resuscitation                                                                                                                                                                                   | Avoid unnecessary mouth-to-mouth contact; use mouthpiece, resuscitation bag, other ventilation devices to prevent contact with mouth and oral secretions.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Soiled patient care equipment                                                                                                                                                                           | Handle in a manner that prevents transfer of microorganisms to oneself, others and to environmental surfaces; wear gloves if visibly contaminated; perform hand hygiene after handling equipment.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Soiled linen and laundry                                                                                                                                                                                | Handle in a manner that prevents transfer of microorganisms to oneself, others, and to environmental surfaces; wear gloves (gown if necessary) when handling and transporting soiled linen and laundry and perform hand hygiene                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Needles and other sharps                                                                                                                                                                                | Use devices with safety features when available; do not recap, bend break or hand-manipulate used needles; if recapping is necessary, use a one-handed scoop technique; place used sharps in a puncture-resistant container.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

**TABLE 1. PANDEMIC INFLUENZA INFECTION CONTROL GUIDANCE FOR HEALTHCARE PROVIDERS (CONT.)**

| RECOMMENDATIONS                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                            |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| COMPONENT                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                            |
| STANDARD PRECAUTIONS (cont.)                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                            |
| Environmental cleaning and disinfection                                                                                                                                         | Use EPA-registered hospital detergent-disinfectant; follow standard facility procedures for cleaning and disinfection of environmental surfaces; emphasize cleaning/disinfection of frequently touched surfaces (e.g., bed rails, phones, lavatory surfaces).                                                              |
| Disposal of solid waste                                                                                                                                                         | Contain and dispose of solid waste (medical and non-medical) in accordance with facility procedures and/or local or state regulations; wear gloves when handling waste; wear gloves when handling waste containers and perform hand hygiene                                                                                |
| Respiratory hygiene/cough etiquette                                                                                                                                             | Have the patient cover the mouth/nose when sneezing/coughing; use tissues and dispose in no-touch receptacle; perform hand hygiene after contact with respiratory secretions; wear a mask (procedure or surgical) if tolerated; sit or stand as far away as possible (more than 3 feet) away from persons who are not ill. |
| Source control measures for persons with symptoms of a respiratory infection; implement at first point of encounter (e.g., triage/reception areas) within a healthcare setting. |                                                                                                                                                                                                                                                                                                                            |
| DROPLET PRECAUTIONS                                                                                                                                                             | <a href="http://www.cdc.gov/ncidod/hip/ISOLAT/droplet_prec_excerpt.htm">www.cdc.gov/ncidod/hip/ISOLAT/droplet_prec_excerpt.htm</a>                                                                                                                                                                                         |
| Patient placement                                                                                                                                                               | Place patients with influenza in a private room or cohort with other patients with influenza.* Keep door closed or slightly ajar; maintain room assignments of patients in nursing homes and other residential settings, and apply droplet precautions to all persons in the room.                                         |
|                                                                                                                                                                                 | *During the early stages of a pandemic, infection with influenza should be laboratory-confirmed, if possible.                                                                                                                                                                                                              |
| Personal protective equipment                                                                                                                                                   | Wear a surgical or procedure mask for entry into patient room; wear other PPE as recommended for standard precautions.                                                                                                                                                                                                     |
| Patient transport                                                                                                                                                               | Limit patient movement outside of room to medically necessary purposes; have patient wear a procedure or surgical mask when outside the room.                                                                                                                                                                              |
| Other                                                                                                                                                                           | Follow standard precautions and facility procedures for handling linen and laundry and dishes and eating utensils, and for cleaning/disinfection of environmental surfaces and patient care equipment, disposal of solid waste, and postmortem care.                                                                       |

**TABLE 1. PANDEMIC INFLUENZA INFECTION CONTROL GUIDANCE FOR HEALTHCARE PROVIDERS (CONT.)**

| COMPONENT                     |                                                                                                                                                                                                                                                                                                                 |
|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEROSOL-GENERATING PROCEDURES | During procedures that may generate small particles of respiratory secretions (e.g., endotracheal intubation, bronchoscopy, nebulizer treatment, suctioning), healthcare personnel should wear gloves, gown, face/eye protection, and a fit-tested N-95 respirator or other appropriate particulate respirator. |

**Standard Precautions for home health care**

Healthcare providers who enter homes where there is a person with an influenza-like illness should follow the recommendations for Standard and Droplet Precautions. Standard Precautions include performing hand hygiene and respiratory hygiene/cough etiquette, wearing gloves and gowns, using face/eye protection when needed; and following safe work practices.

**Droplet Precautions for home health care**

Healthcare providers who enter homes where there is a person with an influenza-like illness should follow the recommendations for Standard and Droplet Precautions. Droplet Precautions include all Standard Precautions plus separating the patient from others in the household as much as possible and wearing a surgical or procedure mask for patient interactions. Professional judgment should be used in determining whether to don a mask upon entry into the home or only on entering the patient's room. Factors to consider in this decision include the possibility that others in the household may be infectious and the extent to which the patient is ambulating within the home.

## APPENDIX 1. CLINICAL PRESENTATION AND COMPLICATIONS OF SEASONAL INFLUENZA

Although often quite characteristic, the clinical picture of seasonal influenza can be indistinguishable from illness caused by other respiratory infections. The frequent use of non-specific terms such as "flu" and "influenza-like illness" makes the clinical diagnosis of influenza even more indefinite. Even when the diagnosis of influenza is confirmed, management can be challenging, as influenza virus infection can result in subclinical infection, mild illness, uncomplicated influenza, or exacerbation of underlying chronic conditions to fulminant deterioration, and can result in a wide variety of complications.

This appendix provides a brief description of the common presentations and complications of seasonal human influenza. Novel and pandemic influenza viruses might, however, cause quite different clinical syndromes than seasonal influenza. For instance, seasonal influenza-related complications more commonly affect those at the extremes of age, whereas previous pandemics resulted in disproportionate morbidity and mortality in young and previously healthy adults. It will be essential to describe and disseminate the clinical features of novel or pandemic influenza cases as soon as they are identified. Appendix 2 includes a brief clinical summary of illnesses associated with previous influenza pandemics and with avian influenza A (H5N1) virus in humans.

### Presentation

- A typical case of uncomplicated seasonal influenza begins abruptly and is manifested by systemic symptoms such as fever, chills, myalgias, anorexia, headache, and extreme fatigue. Fever typically lasts 2–3 days and usually reaches 38–40°C, but can be higher (particularly in children).
- Respiratory tract symptoms such as nonproductive cough, sore throat, and upper respiratory congestion occur at the same time, although these may be overshadowed by systemic complaints.
- Physical examination typically reveals fever, weakness, mild inflammation of the upper respiratory tract, and rare crackles on lung examination, but none of these findings is specific for influenza.
- In uncomplicated illness, major symptoms typically resolve after a limited number of days, but cough, weakness, and malaise can persist for up to 2 weeks.
- In the elderly and in infants, the presenting signs can include respiratory symptoms with or without fever, fever only, anorexia only, lassitude, or altered mental status. In children, fevers are often higher than in adults and can lead to febrile seizures. Gastrointestinal manifestations (e.g., vomiting, abdominal pain, diarrhea) occur more frequently in children. Fever or apnea without other respiratory symptoms might be the only manifestations in young children, particularly in neonates.

Influenza is difficult to distinguish from illnesses caused by other respiratory pathogens on the basis of symptoms alone. Fever and cough, particularly in combination, are modestly predictive of influenza in unvaccinated adults, as is the combination of fever, cough, headache, and pharyngitis in children. Other constitutional signs and symptoms, such as chills, rigors, diaphoresis, and myalgias, are also suggestive. The positive predictive value of any clinical definition is strongly dependent on the level of influenza activity and the presence of other respiratory pathogens in the community.

### Routine laboratory findings

No routine laboratory test results are specific for influenza. Leukocyte counts are variable, although thrombocytopenia and severe leukopenia have been described in fulminant cases. Leukocytosis of >15,000 cells/ml should raise suspicion for a secondary bacterial process. Comprehensive laboratory testing might reveal other influenza-related complications (see below).

## Differential diagnosis

The fever and respiratory manifestations of seasonal influenza are not specific and can occur with several other pathogens, including respiratory syncytial virus (RSV), parainfluenza viruses, adenoviruses, human metapneumovirus, rhinoviruses, coronaviruses, and *Mycoplasma pneumoniae*. In contrast to influenza viruses, most of these pathogens do not usually cause severe disease, particularly in previously healthy adults. RSV and parainfluenza viruses can, however, lead to severe respiratory illness in young children and the elderly and should be considered in the differential diagnosis if circulating in the community. Even if an alternate etiology is determined, viral or bacterial co-infections can still be a possibility.

The tendency for influenza to occur in community epidemics and to affect persons of all ages can sometimes allow the clinician to diagnose seasonal influenza with reasonable certainty in the absence of laboratory testing. Nevertheless, a definitive diagnosis requires laboratory testing. Rapid influenza diagnostic tests and immunofluorescence testing using a panel of respiratory pathogens have become increasingly available for aiding clinical management of patients with suspected influenza. Further information on diagnostic testing for influenza can be found at <http://www.cdc.gov/flu/professionals/labdiagnosis.htm>.

## Complications

### Groups at risk for complications of influenza

The following groups are currently recognized by the Advisory Committee on Immunization Practices (ACIP) to be at higher risk for complications of seasonal influenza (e.g., hospitalization; death) compared to healthy older children and younger adults:<sup>4</sup>

- Persons aged  $\geq 65$  years
- Residents of nursing homes and other chronic-care facilities that house persons of any age who have chronic medical conditions
- Adults and children who have chronic disorders of the pulmonary or cardiovascular systems, including asthma
- Adults and children who required regular medical follow-up or hospitalization during the previous year because of chronic metabolic diseases (including diabetes mellitus), renal dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or by infection with human immunodeficiency virus [HIV])
- Children and adolescents (aged 6 months–18 years) who are receiving long-term aspirin therapy (and are therefore at risk for Reye syndrome)
- Pregnant women
- All children aged  $<2$  years
- All persons with conditions that can compromise respiratory function or the handling of respiratory secretions, or that can increase the risk of aspiration

Excluding the last group, in 2003 approximately 85 million persons in the United States belonged to one or more of these target groups.

### Types of influenza complications

Exacerbations of underlying chronic diseases are the most common serious complications of influenza. Complications are frequently related to underlying respiratory disease, such as chronic obstructive pulmonary disease (COPD). In some cases, typical influenza symptoms might be brief or minimal compared to the exacerbation of the underlying disease, particularly in the elderly.

<sup>4</sup> Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2005;54:1–40 [www.cdc.gov/mmwr/pdf/rr/rr54e713.pdf](http://www.cdc.gov/mmwr/pdf/rr/rr54e713.pdf).

Secondary bacterial pneumonia, another common complication, is characterized by an initial improvement in influenza symptoms over the first few days followed by a return of fever, along with a productive cough and pleuritic chest pain. Findings include lobar consolidation on chest x-ray and, in adults, sputum smears positive for leukocytes and bacteria. The most commonly isolated pathogens are *Streptococcus pneumoniae*, *Staphylococcus aureus*, group A *Streptococcus*, and *Haemophilus influenzae*.

Influenza virus infection can also result in a primary viral pneumonia. A prominent feature of previous influenza pandemics, primary influenza viral pneumonia is currently a relatively rare outcome of seasonal influenza in adults. In contrast, children with pneumonia are more likely to have a viral etiology, including influenza than a bacterial cause. Primary influenza pneumonia usually begins abruptly, with rapid progression to severe pulmonary disease within 1–4 days. Physical and radiologic findings are consistent with diffuse interstitial and/or alveolar disease, including bilateral inspiratory crackles on auscultation and diffuse pulmonary infiltrates on chest radiographs. Hypoxia and hemoptysis indicate a poor prognosis, and recovery can take up to 1–2 weeks. Mixed viral-bacterial pneumonia is slightly more common than primary viral pneumonia, and, although mixed pneumonia may have a slower progression, the two are often indistinguishable. Bacterial pathogens in mixed infections are similar to those found in secondary bacterial pneumonias.

Bronchiolitis due to influenza is more common in children, with a clinical picture similar to that of RSV or parainfluenza virus infections. Influenza is a cause of croup (laryngotracheobronchitis) in children, and, although influenza viruses are a less common etiology than other respiratory viruses, the illness can be more severe. Children with influenza can also develop otitis media, due to either direct viral infection or secondary bacterial involvement. Similarly, bacterial sinusitis can develop in older children and adults with influenza.

Seasonal influenza can cause a range of cardiovascular complications, most commonly as an exacerbation of an underlying condition such as congestive heart failure. Pregnant women and children with congenital heart defects can also experience worsening cardiac function during an influenza illness. Cardiac inflammation, such as myocarditis and pericarditis, can be found occasionally, although clinical manifestations are rare. Available reports suggest that myocarditis might have occurred more frequently during pandemic years. Influenza virus is not typically identified in heart tissue, suggesting that the host inflammatory response might play a role. Although influenza has been associated in rare instances with sudden death possibly due to cardiac arrhythmia, this outcome has been difficult to investigate.

Gastrointestinal involvement is uncommon with seasonal influenza, although more commonly reported in children. Manifestations can include vomiting and diarrhea, sometimes leading to significant dehydration. Transient hepatic inflammation can occur in rare circumstances.

Myositis related to influenza is another complication more commonly found in children, although more frequently associated with influenza B. Involvement may be limited to pain and weakness of the lower extremities but can progress to rhabdomyolysis and renal failure in some cases.

Among the neurologic complications associated with seasonal influenza, uncomplicated self-limited febrile seizures are the most common, usually occurring in younger children with high fever. Influenza-associated encephalopathy, characterized by an acute alteration in mental status within the first few days of fever onset, is a recently recognized complication of influenza in children. Most reports of influenza-associated encephalopathy have been in Japanese children, but the condition has been reported sporadically in other countries, including the United States. The syndrome can include seizures, neurologic deficits, obtundation, and coma. While most children recover completely, some cases can result in permanent sequelae or death. This condition might be due to an abnormal host inflammatory response without viral infection of the central nervous system. Guillain-Barre syndrome and transverse myelitis have been reported to occur in very rare instances after influenza, but no definite etiologic relationship has been established.

Reye syndrome is another serious neurologic complication associated with influenza. It is characterized by an acute encephalopathy combined with hepatic failure in the absence of inflammation in either the brain or the liver. Hepatic

involvement includes fatty infiltration, hypoglycemia, and hyperammonemia, whereas neurologic manifestations include cerebral edema, delirium, coma, and respiratory arrest. Reye syndrome was found to be associated with the use of aspirin in children; its incidence has decreased dramatically since the 1980s after aspirin use was discouraged in children.

Seasonal influenza can be associated with systemic complications, such as sepsis and shock. Sepsis caused by invasive co-infection with *Staphylococcus aureus*, including methicillin-resistant *S. aureus* (MRSA), or other bacteria, such as *Neisseria meningitidis* has been reported. Toxic shock syndrome without bacterial co-infection has also been reported.



## APPENDIX 2. CLINICAL PRESENTATION AND COMPLICATIONS OF ILLNESSES ASSOCIATED WITH AVIAN INFLUENZA A (H5N1) AND PREVIOUS PANDEMIC INFLUENZA VIRUSES

Human infections with different avian influenza A viruses have emerged and caused mild to severe illness in recent years, including H9N2, H7N7, H7N3, and H7N2. One novel subtype, influenza A (H5N1), has repeatedly caused limited outbreaks of severe and fatal human disease in recent years and therefore has been of particular concern.

### Human infection with avian influenza A (H5N1)

The H5N1 subtype first came to widespread public attention in 1997, when a poultry outbreak of highly pathogenic avian influenza A (H5N1) in Hong Kong caused illness in 18 humans. These cases were the first identified instances of direct avian-to-human transmission of an avian influenza A virus that led to severe disease. Clinical features ranged from asymptomatic infection or mild upper respiratory symptoms to severe pneumonia and death. Most cases presented with fever, headache, malaise, myalgia, sore throat, cough, and rhinorrhea; a few persons also had conjunctivitis or gastrointestinal distress. Seven persons, mostly children, developed only mild upper respiratory infections, whereas 11 developed severe primary viral pneumonia with rapid deterioration. Most patients in this latter group developed lymphopenia; six developed acute respiratory distress syndrome (ARDS), and five developed multi-organ system failure. Other abnormalities included pulmonary hemorrhage, renal dysfunction, liver failure, pancytopenia, hemophagocytosis, and Reye syndrome (with aspirin ingestion). Notably, none of the patients had secondary bacterial pneumonia. Six of the 18 infected persons eventually died.

Avian influenza A (H5N1) resurfaced in Hong Kong in February 2003, in a father and son returning from Fujian Province, China. Both presented with influenza-like symptoms, chest radiograph abnormalities, and lymphopenia. The father's status rapidly deteriorated, and he developed severe lung involvement and hemophagocytosis; the 8-year-old son recovered. Of note, the father's 7-year-old daughter had also died of a pneumonia-like illness while in China, but the cause of her illness was not determined. The boy reported close contact with live chickens during his visit to China, but no definite source for H5N1 was found.

The most recent human outbreak of avian influenza A (H5N1) has been ongoing since December 2003. This outbreak has been associated with an extensive H5N1 epizootic among poultry in Asia. Transmission continues to be predominantly from birds to humans, although a few instances of limited human-to-human transmission have been suspected.

Reports published from Vietnam and Thailand describe the early confirmed H5N1 cases from this outbreak. These reports characterize human illness with avian influenza A (H5N1) virus infection as a primarily respiratory febrile illness that progresses to severe disease in a high proportion of cases. Among 10 Vietnamese patients,<sup>5</sup> all were previously healthy children or young adults (mean age, 13.7 years) who presented to medical attention with fever, cough, and dyspnea. None of the patients had other respiratory symptoms, such as sore throat or rhinorrhea, but seven developed diarrhea. Significant lymphopenia was observed in all 10 cases, and moderate thrombocytopenia occurred. All 10 had marked abnormalities on chest radiograph, and eight patients—all of whom eventually died—required mechanical ventilation for respiratory failure. Respiratory cultures suggested bacterial pneumonia in two patients.

Of 12 cases described from Thailand,<sup>6</sup> seven were aged <14 years, and all but one were previously healthy. All of the patients developed fever, cough, and dyspnea, and six patients were reported with myalgia and diarrhea. Decreased leukocyte counts were reported in seven cases, thrombocytopenia occurred in four cases, and increased serum liver enzymes were found in eight.

<sup>5</sup> Tran TH, Nguyen TL, Nguyen TD, Luong TS, Pham PM, Nguyen VC, et al. Avian influenza A (H5N1) in 10 patients in Vietnam. *N Engl J Med*. 2004;350:1179-88.

<sup>6</sup> Chotpitayasunondh T, Ungchusak K, Hanshaoworakul W, Chunsuthiwat S, Sawanpanyalert P, Kijphati R, et al. Human disease from influenza A (H5N1), Thailand, 2004. *Emerg Infect Dis*. 2005;11:201-9.

All patients had negative blood cultures. They all had abnormal chest radiographs; nine developed respiratory failure with ARDS, whereas five developed cardiac failure, four had renal failure, and eight ultimately died. In the Vietnamese and Thai cases, respiratory deterioration occurred a median of 5 days after symptom onset, but the range was quite wide.

Whereas all patients described above presented with pulmonary symptoms, subsequently published case reports suggest that other clinical syndromes can occur with H5N1 infection.<sup>7,8,9</sup> In one report, a 39-year-old female with confirmed H5N1 from Thailand was initially admitted with symptoms of fever, vomiting, and diarrhea, and was found to have significant lymphopenia. She developed shortness of breath approximately 12 days after illness onset and soon progressed to ARDS and death. A 4-year-old male from Vietnam presented for medical attention with severe diarrhea, developed acute encephalitis with coma, and died soon thereafter. Although avian influenza A (H5N1) was later detected in throat, stool, serum, and cerebrospinal fluid specimens, the patient had no respiratory symptoms at presentation. This patient's 9-year-old sister died of a similar illness a few days before his illness began, but no H5N1 testing was performed. Asymptomatic H5N1 infection, detected by seroconversion, has been reported.

Updated information on avian influenza can be found at [http://www.who.int/csr/disease/avian\\_influenza/en/](http://www.who.int/csr/disease/avian_influenza/en/).

### Illnesses associated with previous pandemic viruses

Since most people do not have previous immunity to novel influenza A viruses, an influenza pandemic results in an increased rate of severe disease in a majority of age groups. Nevertheless, the three pandemics of the past century demonstrated significant variability in terms of morbidity. The 1918–19 pandemic was particularly notable in affecting young, healthy adults with severe illness. A significant proportion of patients developed fulminant disease, accompanied by a striking perioral cyanosis, leading to death within a few days. Postmortem examinations in these patients frequently revealed denuding tracheobronchitis, pulmonary hemorrhage, or pulmonary edema. Others survived the initial illness, only to die of a secondary bacterial pneumonia, usually due to *Streptococcus pneumoniae*, *Staphylococcus aureus*, group A *Streptococcus*, or *Haemophilus influenzae*.

The clinical features of the subsequent pandemics of 1957–58 and 1968–69 were also typical of influenza-like illness, including fever, chills, headache, sore throat, malaise, cough, and coryza, but were milder compared to the 1918–19 pandemic. On a population level, the impact of influenza in 1957–58 was only one-tenth that observed in 1918–19, and the excess death rate in 1968–69 was only half that observed during 1957–58. However, death rates were elevated among the chronically ill and the elderly, and the occurrence of severe complications, such as primary viral pneumonia, was notably increased in healthy young adults during the 1957–58 pandemic, particularly in pregnant women.

### Implications for the next pandemic

The characteristic clinical features of the next influenza pandemic cannot be predicted. It is reasonable to assume that most affected persons will have the typical features of influenza (e.g., fever, respiratory symptoms, myalgia, malaise). However, past pandemics have varied considerably with regard to severity and associated complications. Illnesses caused by novel influenza viruses such as avian influenza A (H5N1) might predict the potential characteristics of pandemic influenza, but H5N1 has not adapted to spread easily among humans, and its presentation and severity might change as the virus evolves. Even as the next pandemic begins and spreads, the characteristic features might change, particularly if successive waves occur over several months. Given this potential for a dynamic clinical picture, it will be important for clinicians and public health partners to work together to disseminate updated and authoritative information to the healthcare community on a regular basis.

<sup>7</sup> de Jong MD, Bach VC, Phan TQ, Vo MH, Tran TT, Nguyen BH, et al. Fatal avian influenza A (H5N1) in a child presenting with diarrhea followed by coma. *N Engl J Med*. 2005;352:686–91.

<sup>8</sup> Apisarnthanarak A, Kitphati R, Thongphubeth K, Patoomanunt P, Anthanont P, Auwanit W, et al. Atypical avian influenza (H5N1). *Emerg Infect Dis* 2004;10:1321–4.

<sup>9</sup> Beigel JH, Farrar J, Hayden FG, Hyer R, de Jong MD, Lochindrat S, et al. Avian influenza A (H5N1) infection in humans. *N Eng J Med*. 2005 Sep 29;353(13):1374–85.

## APPENDIX 3. GUIDELINES FOR MANAGEMENT OF COMMUNITY-ACQUIRED PNEUMONIA, INCLUDING POST-INFLUENZA COMMUNITY-ACQUIRED PNEUMONIA

### Rationale

Post-influenza bacterial community-acquired pneumonia will likely be a common complication during the next pandemic and might affect approximately 10% of persons with pandemic influenza, based on data from previous influenza pandemics. Assuming that pandemic influenza will affect about 15%–35% of the U.S. population, approximately 4.4 to 10.2 million cases of post-influenza bacterial community-acquired pneumonia could occur.

Post-influenza bacterial community-acquired pneumonia often presents as a return of fever, along with a productive cough and pleuritic chest pain, after an initial improvement in influenza symptoms over the first few days. Findings include lobar consolidation on chest x-ray and, in adults, sputum smear positive for leukocytes and bacteria. As with other bacterial infections, leukocytosis with increased immature forms may be present, but this finding is neither sensitive nor specific. The most common etiologies of post-influenza bacterial pneumonia are *Streptococcus pneumoniae*, *Staphylococcus aureus*, group A *Streptococcus*, and *Haemophilus influenzae*. Primary viral pneumonia, with abrupt onset and rapid progression, is more common than bacterial pneumonia in children, yet rare in adults. Physical and radiologic findings in viral pneumonia are consistent with interstitial and/or alveolar disease and include bilateral inspiratory crackles and diffuse infiltrates. Mixed viral-bacterial pneumonia is slightly more common than primary viral pneumonia, but they are often indistinguishable. Bacterial pathogens in mixed infections are similar to those found in secondary bacterial pneumonias. Droplet and Standard Precautions are currently recommended for community-acquired pneumonia of bacterial etiology.<sup>9</sup>

Treatment of community-acquired pneumonia, including post-influenza bacterial community-acquired pneumonia will pose challenges for clinicians during a pandemic. Secondary bacterial pneumonia following influenza virus infection will be difficult to distinguish from community-acquired pneumonia that is not preceded by influenza. Current guidelines for the treatment of adult community-acquired pneumonia (CAP) during the Interpandemic Period de-emphasize the use of diagnostic testing for pathogen-directed treatment and favor empiric therapy with safe and effective broad-spectrum antibacterials, especially extended-spectrum macrolides and fluoroquinolones. However, these antibacterials will likely be in short supply during a pandemic.

The guidelines in this appendix are therefore designed to assist clinicians in managing patients with community-acquired pneumonia, including post-influenza bacterial community-acquired pneumonia, in a setting of high patient volume and limited clinical resources, where the pressure to treat empirically will likely be even greater than during the Interpandemic Period. For adults, the guidance draws heavily from the current draft guidelines for the management of CAP developed jointly by the Infectious Diseases Society of America (IDSA) and the American Thoracic Society (ATS).<sup>10,11</sup> For children, the guidance incorporates recommendations from the British Thoracic Society (BTS),<sup>12</sup> a published review,<sup>13</sup> and expert opinion.

<sup>9</sup> Centers for Disease Control and Prevention. Guidelines for preventing health-care-associated pneumonia, 2003 recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee. *Respir Care*. 2004;49(8):926–39.

<sup>10</sup> Mandell LA, Bartlett JG, Dowell SF, File TM Jr, Musher DM, Whitney C; Infectious Diseases Society of America. Update of practice guidelines for the management of community-acquired pneumonia in immunocompetent adults. *Clin Infect Dis*. 2003; 37(11):1405–33.

<sup>11</sup> Niederman MS, Mandell LA, Anzueto A, Bass JB, Broughton WA, Campbell GD, et al. American Thoracic Society. Guidelines for the management of adults with community-acquired pneumonia. Diagnosis, assessment of severity, antimicrobial therapy, and prevention. *Am J Respir Crit Care Med*. 2001;163(7):1730–54.

<sup>12</sup> British Thoracic Society Standards of Care Committee. British Thoracic Society guidelines for the management of community acquired pneumonia in childhood. *Thorax*. 2002;57(suppl 1):i1–24.

<sup>13</sup> McIntosh, K. Community-acquired pneumonia in children. *N Engl J Med*. 2002;346:429–37.

## Prevention

Efforts to maximize vaccination coverage against *Streptococcus pneumoniae* is an important component of post-influenza bacterial community-acquired pneumonia prevention during the Interpandemic, Pandemic Alert, and Pandemic Periods. Current guidelines on the use of the 23-valent pneumococcal polysaccharide vaccine among adults and the 7-valent pneumococcal conjugate vaccine among children are available.<sup>14,15</sup>

### Site of care: inpatient versus outpatient

#### Adults

- IDSA-ATS draft guidelines recommend the use of severity scores, such as the Pneumonia PORT Severity Index (PSI) and the CURB-65 system,<sup>16,17</sup> to determine which patients can be safely treated as outpatients (Tables 2–5). The use of these or other similar systems could be extremely important during the next pandemic, as hospital beds will be in short supply. However, these systems should be used to supplement rather than replace the judgment of the individual clinician.

#### Children

- Current guidelines provide indicators for hospitalization of children with CAP. For infants, the indications include temperature >38.5 C, respiratory rate (RR) >70 breaths per minute, chest retractions (indrawing), nasal flaring, hypoxia, cyanosis, intermittent apnea, grunting, and poor feeding. Indications for hospitalization among older children include temperature >38.5 C, RR >50, chest retractions, nasal flaring, hypoxia, cyanosis, grunting, and signs of dehydration.

As with pandemic influenza, the decision to hospitalize for post-influenza bacterial community-acquired pneumonia during the Pandemic Period will rely on the physician's clinical assessment of the patient as well as availability of personnel and hospital resources. Although an unstable patient will be considered a high priority for admission, patients with certain high-risk conditions (see Appendix 1) might also warrant special attention. Home management with follow-up might be appropriate for well-appearing young children with fever alone.

<sup>14</sup> Prevention of pneumococcal disease among infants and young children: recommendations of the Advisory Committee on Immunization Practices. MMWR Morb Mortal Wkly Rep. 2000;49(RR-9).

<sup>15</sup> CDC. Prevention of pneumococcal disease: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Morb Mortal Wkly Rep. 1997;46(RR-8).

<sup>16</sup> Fine MJ, Auble TE, Yealy DM, Hanusa BH, Weissfeld LA, Singer DE, et al. A prediction rule to identify low-risk patients with community-acquired pneumonia. *N Engl J Med*. 1997;336(4):243–50..

<sup>17</sup> Lim WS, van der Eerden MM, Laing R, Boersma WG, Karalus N, Town GI, et al. Defining community acquired pneumonia severity on presentation to hospital: an international derivation and validation study. *Thorax*. 2003;58(5):377–82.

**TABLE 2. PNEUMONIA PORT SEVERITY INDEX (PSI) CALCULATION**

| Patient Characteristic                  | Points Assigned    |
|-----------------------------------------|--------------------|
| Demographic Factor                      |                    |
| Age                                     |                    |
| Male                                    | Number of years    |
| Female                                  | Number of years–10 |
| Nursing home resident                   | +10                |
| Comorbid illnesses                      |                    |
| Neoplastic disease                      | +30                |
| Liver disease                           | +20                |
| Congestive heart failure                | +10                |
| Cerebrovascular disease                 | +10                |
| Renal disease                           | +10                |
| Physical examination finding            |                    |
| Altered mental status                   | +20                |
| Respiratory rate >30 breaths/minute     | +20                |
| Systolic blood pressure <90 mm Hg       | +20                |
| Temperature <35°C or >40°C              | +15                |
| Pulse >125 beats/minute                 | +10                |
| Laboratory and /or radiographic finding |                    |
| Arterial pH <7.35                       | +30                |
| Blood urea nitrogen >30 mg/dl           | +20                |
| Sodium <130mmol/l                       | +20                |
| Glucose >250 mg/dl                      | +10                |
| Hematocrit <30%                         | +10                |
| Hypoxemia                               | +10                |
| <90% by pulse oximetry OR               |                    |
| <60mm Hg by arterial blood gas          |                    |
| Pleural effusion on baseline radiograph | +10                |

**TABLE 3. PNEUMONIA SEVERITY INDEX RISK CLASSIFICATION**

| PSI Risk Class | Characteristics and Points                                                             | Recommended Site of Care     |
|----------------|----------------------------------------------------------------------------------------|------------------------------|
| I              | Age >50 years + no comorbid conditions, normal range vital signs, normal mental status | Outpatient                   |
| II             | <70                                                                                    | Outpatient                   |
| III            | 71–90                                                                                  | Outpatient / Brief inpatient |
| IV             | 91–130                                                                                 | Inpatient                    |
| V              | >130                                                                                   | Inpatient                    |

**TABLE 4. CURB-65 SCORING SYSTEM**

| Characteristic                                       | Points |
|------------------------------------------------------|--------|
| Confusion <sup>1</sup>                               | +1     |
| Urea >7mmol/l (20mg/dl)                              | +1     |
| Respiratory rate >30 breaths per minute              | +1     |
| Blood pressure (Systolic <90 or diastolic <60 mm Hg) | +1     |
| Age >65 years                                        | +1     |

<sup>1</sup> Based on a specific mental test or disorientation to person, place, or time.

**TABLE 5. RECOMMENDED SITE OF CARE BASED ON CURB-65 SYSTEM**

| Number of Points | Recommended Site of Care     |
|------------------|------------------------------|
| 0–1              | Outpatient                   |
| 2                | Admit to medical ward        |
| 3–5              | Admit to medical ward or ICU |

## Diagnostic testing

### Adults

Generally, the etiologies associated with CAP during the Interpandemic Periods will continue to occur during a pandemic. Familiarity with the appropriate use of available diagnostic tests is therefore a key feature of clinical preparedness.

- Draft IDSA-ATS guidelines recommend obtaining appropriate specimens for etiologic diagnosis whenever such an etiology would alter clinical care. Given that the most common etiologies of post-influenza bacterial community-acquired pneumonia—*S. pneumoniae* and *S. aureus*, including community-acquired methicillin-resistant *S. aureus* (CA-MRSA)—are treated differently, diagnostic testing should be performed to the extent feasible to distinguish among these pathogens.
- For hospitalized patients, blood cultures, pneumococcal urine antigen testing, and pleural fluid aspiration with Gram stain and culture should be considered.
- Because the diagnostic utility of sputum Gram stain and culture is highly dependent on patient and technical conditions, these are considered optional for hospitalized but non-severe patients.
- For patients admitted to an ICU, aspiration and Gram stain and bacterial culture of endotracheal secretions might also be useful.

### Children

Diagnostic studies for identifying bacterial pneumonia in young children are severely limited.

- Blood cultures should be obtained from all children suspected of having post-influenza bacterial community-acquired pneumonia.
- Sputum samples are rarely useful in children, but tracheal or pleural fluid aspirates—if available—should be submitted for Gram stain and bacterial culture.
- If pleural effusions are present, they should be aspirated and submitted for Gram stain and culture.
- When feasible, antibiotic susceptibility testing of any bacterial isolates is encouraged to direct treatment.

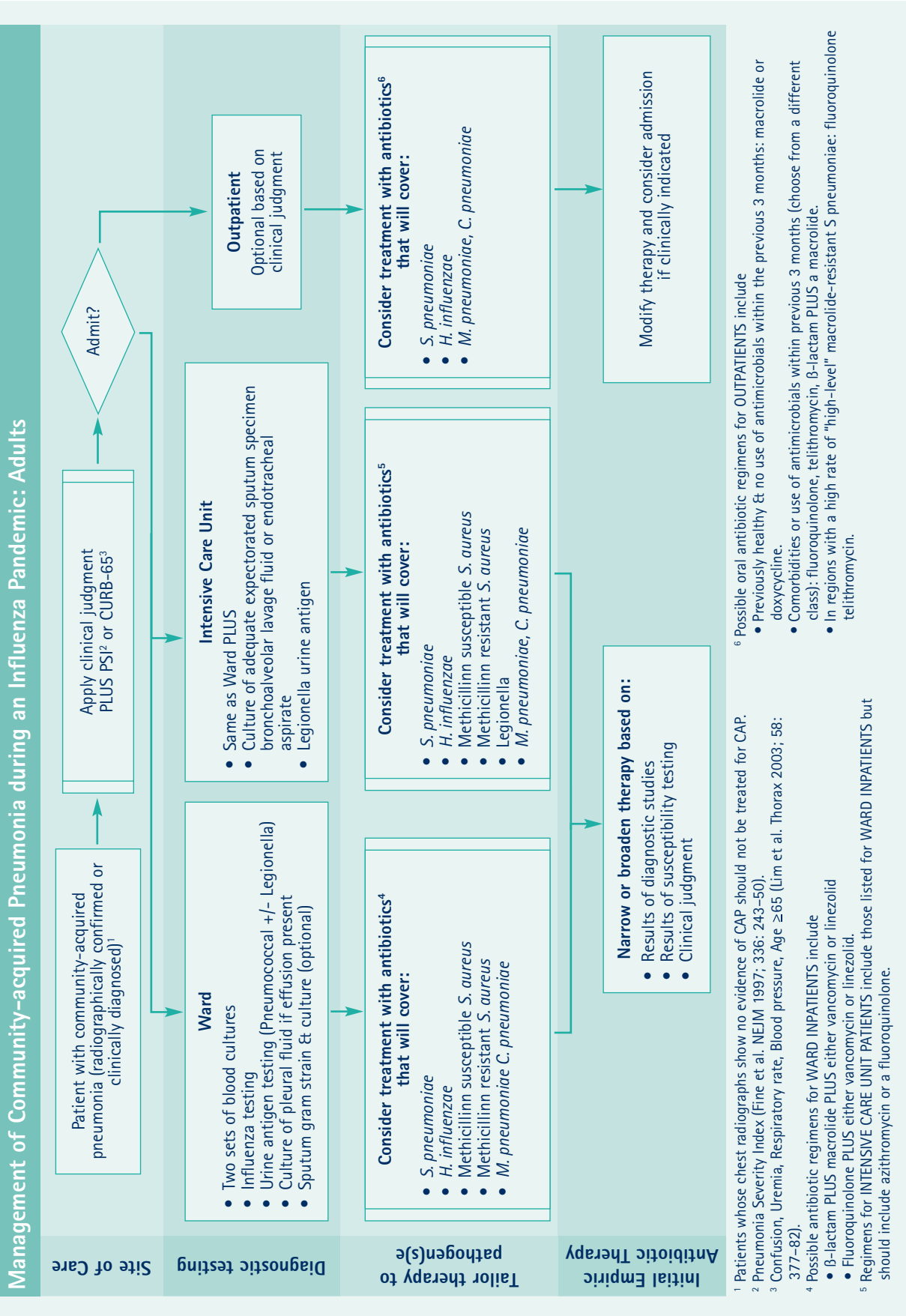
## Antibiotic treatment

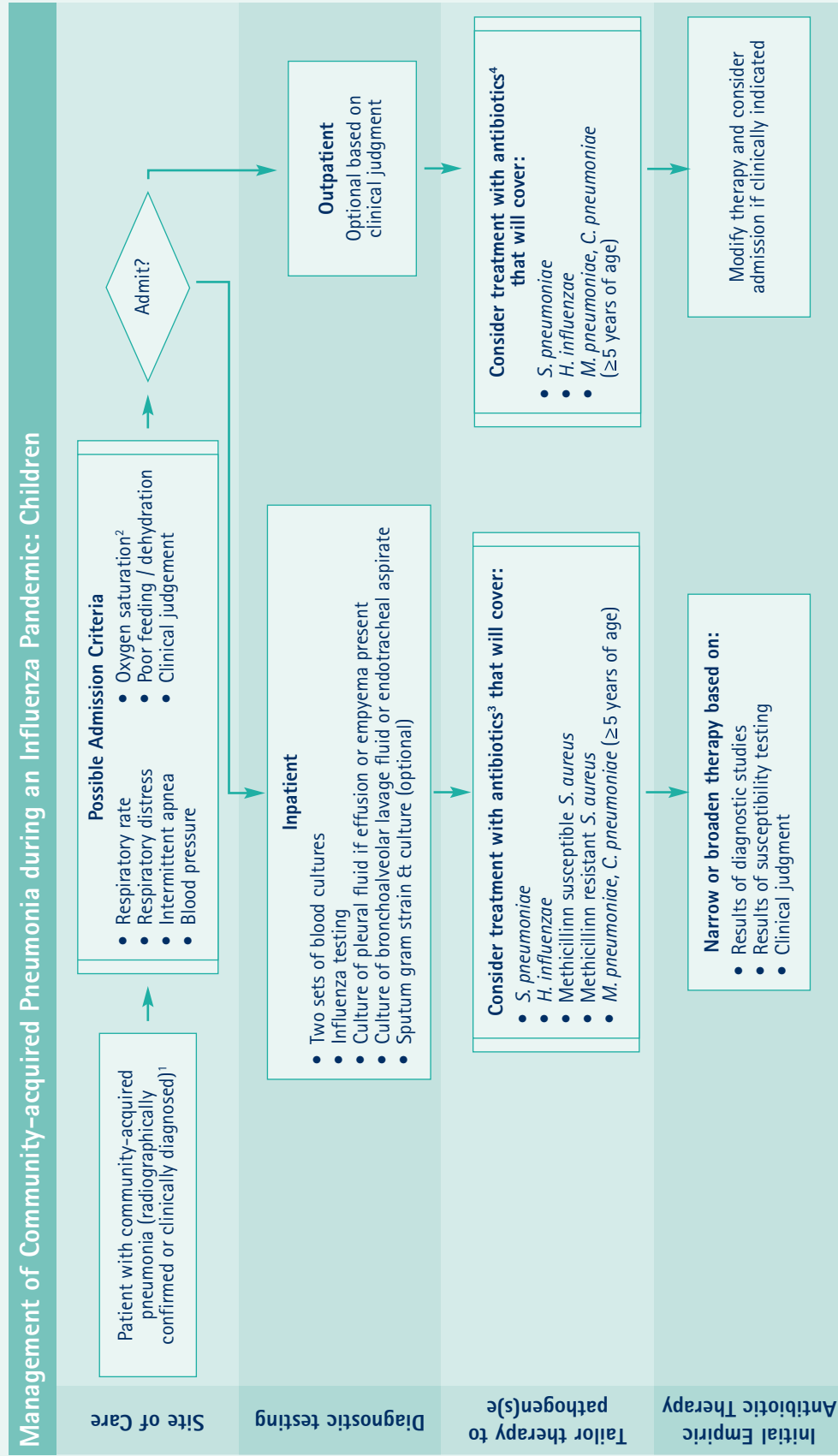
### Adults and children

Antibiotics, particularly those needed to treat CAP, will likely be in short supply during the Pandemic Period. Therefore, use of empiric therapy for all persons with post-influenza bacterial community-acquired pneumonia will likely not be feasible. Antimicrobial therapy will have to be driven by culture and susceptibility testing of appropriate clinical specimens and by awareness of local antibiotic susceptibility patterns. (See Figures 1 and 2.)

- A history of preceding influenza-like illness, especially when pandemic influenza is circulating in the community, might help to screen patients.
- Empiric therapy in adults should be directed toward the most likely etiologies of post-influenza bacterial community-acquired pneumonia.
- Concurrent antiviral treatment might also be beneficial, depending on the timing and presentation of illness (see Supplement 7).



**FIGURE 3. MANAGEMENT OF COMMUNITY-ACQUIRED PNEUMONIA DURING AN INFLUENZA PANDEMIC: ADULTS**

**FIGURE 4. MANAGEMENT OF COMMUNITY-ACQUIRED PNEUMONIA DURING AN INFLUENZA PANDEMIC: CHILDREN**

<sup>1</sup> Although chest radiography is not necessary to make the diagnosis in all pediatric patients with CAP, patients who do undergo chest radiography and whose radiographs show no evidence of CAP should not be treated for CAP.

<sup>2</sup> Pulse oximetry should be performed for all children hospitalized with CAP.

<sup>3</sup> Possible antibiotic regimens for INPATIENTS include:

- Children <5 years of age: β-lactam (e.g. Ampicillin, Amoxicillin, Amoxicillin/clavulanic acid, 3<sup>rd</sup> generation cephalosporin [cefotaxime, ceftriaxone]) PLUS either vancomycin or linezolid.
- Children ≥5 years of age: β-lactam PLUS macrolide PLUS either vancomycin or linezolid.

<sup>4</sup> Possible oral antibiotic regimens for OUTPATIENTS include:

- Children <5 years of age: β-lactam (e.g. Amoxicillin, Amoxicillin/clavulanic acid).
- Children ≥5 years of age: β-lactam (e.g. Amoxicillin, Amoxicillin/clavulanic acid) or a macrolide depending on clinical severity. *M. pneumoniae* & *C. pneumoniae* generally present with less severe illness than *S. pneumoniae* or *H. influenzae*.





# supplement 6 vaccine distribution and use TABLE OF CONTENTS

|                                                                                           |       |
|-------------------------------------------------------------------------------------------|-------|
| SUMMARY OF PUBLIC HEALTH ROLES AND RESPONSIBILITIES FOR VACCINE DISTRIBUTION AND USE..... | S6-2  |
| S6-I. RATIONALE .....                                                                     | S6-4  |
| S6-II. OVERVIEW .....                                                                     | S6-4  |
| S6-III. RECOMMENDATIONS FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS.....             | S6-4  |
| A. Vaccination against seasonal influenza virus strains.....                              | S6-4  |
| B. Preparedness planning for vaccination against a pandemic influenza virus .....         | S6-5  |
| 1. Vaccination of priority groups.....                                                    | S6-5  |
| 2. Vaccine procurement and distribution.....                                              | S6-6  |
| a) Second-dose vaccination .....                                                          | S6-6  |
| b) Contingency planning for Investigational New Drug use .....                            | S6-7  |
| 3. Vaccine monitoring and data collection .....                                           | S6-7  |
| a) Vaccine effectiveness .....                                                            | S6-7  |
| b) Vaccine supply and distribution.....                                                   | S6-7  |
| c) Vaccine coverage .....                                                                 | S6-8  |
| d) Vaccine safety.....                                                                    | S6-8  |
| 4. Public health communications.....                                                      | S6-8  |
| 5. Coordination with bordering jurisdictions.....                                         | S6-9  |
| 6. Legal preparedness.....                                                                | S6-9  |
| 7. Training.....                                                                          | S6-9  |
| S6-IV. RECOMMENDATIONS FOR THE PANDEMIC PERIOD .....                                      | S6-9  |
| A. Before a vaccine is available .....                                                    | S6-9  |
| B. When a vaccine becomes available.....                                                  | S6-10 |
| Box 1. Development of Vaccines Against Pandemic Strains of Influenza .....                | S6-11 |
| Appendix. Resources for Mass Vaccination against Pandemic Influenza.....                  | S6-12 |

## SUMMARY OF PUBLIC HEALTH ROLES AND RESPONSIBILITIES FOR VACCINE DISTRIBUTION AND USE

The roles and responsibilities of healthcare partners in vaccine distribution and use are described in Supplement 3.

### INTERPANDEMIC AND PANDEMIC ALERT PERIODS

#### State and local health departments:

- Work with healthcare partners and other stakeholders to develop state-based plans for vaccine effectiveness, safety, distribution and use.

#### HHS agencies:

- Work with manufacturers to expedite public-sector vaccine purchasing contracts during a pandemic.
- Establish mechanisms for vaccine procurement and distribution.
- Develop guidance on priority groups for vaccination.
- Develop and stockpile vaccine for influenza strains with pandemic potential.
- Expedite the rapid development, licensure, and production of new influenza vaccines, as well as evaluate dose optimization strategies to maximize use of limited vaccine stocks.
- Estimate rates of reports of mild and severe adverse events following immunization (AEFIs) that may occur with mass influenza vaccination, and improve capacity for responding to them.
- Identify mechanisms and define protocols for conducting vaccine-effectiveness studies.
- Develop a system for monitoring state-specific vaccine coverage rates at regular intervals, using a pre-existing population-based survey.
- Develop reporting specifications for tracking data on vaccine administration and provide a vaccine database for optional use by states.
- Develop and distribute communication and education materials for use by states and other stakeholders.

### PANDEMIC PERIOD

**After the first reports of pandemic influenza are confirmed and before a pandemic vaccine becomes available**

#### State and local health departments:

- If stockpiled vaccine of the pandemic subtype is available, work with healthcare partners and other stakeholders to distribute, deliver, and administer vaccines to designated groups.
- Mobilize healthcare partners, and prepare to activate state-based plans for distributing and administering vaccines.
- Keep the healthcare and public health workforce up-to-date on projected timelines for availability of vaccines against pandemic influenza.
- Review modifications, if any, to recommendations on vaccinating priority groups.
- Accelerate training in vaccination and vaccine monitoring for public health staff and for partners responsible for vaccinating priority groups.

## PANDEMIC PERIOD (CONT.)

- Work with other governmental agencies and non-governmental organizations to ensure effective public health communications.

### HHS agencies:

- Facilitate vaccine procurement, distribution, and tracking, working with private partners.
- Revise recommendations on vaccination of priority groups, guided by epidemiologic information about the pandemic virus (e.g., virulence, transmissibility, drug resistance, geographic spread, age-specific attack rates, morbidity and mortality rates).
- Provide state and local partners with guidance on reporting specifications for tracking administration of vaccine doses, to be used when vaccine becomes available.
- Provide state and local partners with guidance on Investigational New Drug (IND) and Emergency Use Authorization (EUA) procedures if new types of influenza vaccines for pandemic purposes are developed but not yet FDA approved.
- Provide guidance to state and local health departments on which adverse event reports are highest priority for investigation.
- Provide regulatory guidance to vaccine manufacturers for the manufacture and shipment of pandemic vaccines.

### After a vaccine becomes available

#### State and local health departments:

- Work with healthcare partners and other stakeholders to distribute, deliver, and administer pandemic vaccines to priority groups.
- Monitor vaccine supplies, distribution, and use.
- Monitor and investigate adverse events.
- Phase-in vaccination of the rest of the population after priority groups have been vaccinated.
- Provide updated information to the public via the news media.
- Work with federal partners to evaluate vaccine-related response activities when the pandemic is over.

### HHS agencies:

- Provide forecasts of pandemic vaccine availability from manufacturers.
- Continue to provide input into appropriate strain selection for seasonal influenza vaccine.
- Distribute public stocks of vaccines to state and large city health departments and to federal agencies with direct patient care responsibility, as needed.
- Implement protocols for assessing vaccine effectiveness.
- Monitor vaccine coverage rates.

## S6-I. RATIONALE

The initial response to an influenza pandemic will include medical care, community containment and personal protective measures, and targeted use of antiviral drugs. Before a vaccine containing the circulating pandemic virus strain becomes available, pre-pandemic vaccine from stockpiles (if available for the pandemic subtype or partially cross-protective to the circulating virus) may be considered for persons in designated priority groups. Once a vaccine against the circulating pandemic virus strain becomes available, its distribution and delivery will be a major focus of pandemic response efforts.

Public health goals for vaccination during an influenza pandemic include:

- Developing pre-pandemic strategies for vaccine manufacturing and stockpiling that will maximize manufacturing capability
- Stockpiling influenza vaccine for strains and subtypes with pandemic potential
- Expediting development of a pandemic virus reference strain and distribution of the strain to vaccine manufacturers
- Accelerating production of a pandemic vaccine
- Maximizing the immune response to the vaccine
- Ensuring efficient and equitable distribution of pandemic vaccine, according to priority lists
- Rapidly determining vaccine effectiveness
- Providing ongoing and timely monitoring of vaccine coverage
- Providing ongoing and timely monitoring of vaccine safety

## S6-II. OVERVIEW

Supplement 6 provides recommendations to state and local partners and other stakeholders on planning for the different elements of a pandemic vaccination program. The recommendations for the Interpandemic and Pandemic Alert Periods focus on planning for vaccine distribution, vaccination of priority groups, monitoring of adverse events, tracking of vaccine supply and administration, vaccine coverage and effectiveness studies, communications, legal preparedness, and training. The recommendations for the Pandemic Period focus on working with healthcare partners to implement plans for vaccination against pandemic influenza and initiate monitoring activities.

The activities described below are primarily the responsibility of government health authorities at the state, federal, local, and tribal levels. Additional issues that might be of interest to healthcare partners that administer vaccine are addressed in Supplement 3.

## S6-III. RECOMMENDATIONS FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS

### A. Vaccination against seasonal influenza virus strains

During the Interpandemic Period, state and local health departments should work with healthcare partners to enhance levels of 1) seasonal influenza vaccination in groups at risk for severe influenza and in healthcare workers, and 2) pneumococcal polysaccharide vaccination among those for whom it is recommended.

The success of the pandemic influenza vaccination program will be determined in large part by the strength of state and local vaccination programs during the Interpandemic Period. Higher annual vaccination rates will foster increased familiarity with



and public confidence in influenza vaccines, increased manufacturing capacity for influenza vaccines, and strengthened distribution channels. HHS is working with industry partners to ensure that influenza vaccine can be produced on an emergency basis at any time throughout the year (see Box 1).

Increased use of pneumococcal polysaccharide vaccine may decrease rates of secondary bacterial infections during a pandemic. Because large-scale pneumococcal vaccination might not be feasible once a pandemic occurs, the Interpandemic Period and Pandemic Alert is the ideal time to deliver this preventive measure. Pneumococcal vaccine is indicated for most persons for whom influenza vaccine is recommended. For specific guidelines on the prevention of pneumococcal disease, please see the Recommendations of the Advisory Committee on Immunization Practices (ACIP) (<http://www.cdc.gov/mmwr/pdf/rr/rr4608.pdf>).

## **B. Preparedness planning for vaccination against a pandemic influenza virus**

A limited amount of avian influenza A (H5N1) vaccine is being stockpiled and will be considered for early use in the event of an H5N1 pandemic. Development of vaccines against other strains with pandemic potential is also being considered. A monovalent vaccine directed against the circulating pandemic virus strain of influenza should begin to be available within 4–6 months after identification of the new pandemic virus strain (Box 1). The number of persons who may be protected by vaccination depends on the manufacturing capacity, the amount of antigen per dose needed for a protective immune response, and the number of doses required. Although annual influenza vaccine is immunogenic in older children and adults with a single 15 microgram ( $\mu\text{g}$ ) dose, a higher antigen concentration and/or two doses may be needed for pandemic vaccine where persons have no previous exposure to the influenza subtype and lack any immunity. Preliminary results from a recent clinical trial of an H5N1 vaccine in healthy adults suggested that two doses of 90  $\mu\text{g}$  were required. Additional clinical trials are ongoing to evaluate possible ways to improve the immune response to lower the amounts of vaccine antigen needed for protection.

Initial pandemic vaccine stocks will be used to vaccinate designated priority groups (Part 1, Appendix D). After vaccination of these priority groups, vaccination of all those who desire it will be phased in depending on available supplies.

In working with healthcare partners to develop state-based plans for distributing vaccines, state and local health departments might use existing state-based plans for emergency mass distribution of medical supplies as the basis for developing local pandemic vaccination plans (e.g., smallpox and bioterrorism response plans).

### **1. Vaccination of priority groups**

A list of priority groups for receiving vaccination and the rationale for prioritization is provided in Part 1, Appendix D, as interim recommendations. In addition, during a pandemic, changes may be made based on the characteristics of the causative virus (e.g., transmissibility, virulence, initial geographic distribution, age-specific attack rates, complication rates) and on vaccine effectiveness.

To prepare for vaccination of priority groups, state and local health departments should:

- Identify a process for reviewing national recommendations for pandemic influenza vaccination and developing state-specific modifications or refinements in priority groups, depending on local circumstances.
- Develop specific definitions for priority groups (e.g., public safety workers, essential service providers) identifying occupational categories and sub-categories, as needed, within each broad priority.
- Estimate the size of relevant priority groups.
- Develop a plan on how persons in priority groups would be identified at vaccination clinics and how vaccine would most efficiently be provided to those groups.
- Educate professional organizations and other stakeholders about the need for priority groups and the rationale for the groups currently recommended.

## 2. Vaccine production, procurement and distribution

HHS is working to expand pandemic influenza vaccine production capacity and will signal to manufacturers when to shift from annual to pandemic vaccine production and assure that pandemic vaccine is produced at full capacity.

At the onset of an influenza pandemic, HHS, in concert with the Congress in collaboration with the States, will work with the pharmaceutical industry to acquire vaccine directed against the pandemic strain. Distribution of pandemic vaccine to health departments and providers will occur via private-sector vaccine distributors or directly via manufacturer. (Only stockpiled pre-pandemic vaccine would be distributed by the federal government, if used.)

Each state and federal agency with direct patient care responsibility will receive available vaccine in proportion to the size of its population in defined priority groups. For priority groups that have been identified, state and local health departments should:

- Determine whether vaccine will be shipped directly from the manufacturer to vaccine providers or to public health clinics for further distribution
- Identify organizations that will provide vaccination to persons in priority groups (e.g., local health departments, occupational health clinics, private clinics identified by the employer or union of an occupational group)
- Identify contacts in and obtain written commitments from each clinic or facility responsible for vaccinating a priority group
- Work with these contacts to develop strategies for rapid distribution and administration of vaccines, taking into account vaccine security issues, cold chain requirements, and transport and storage issues
- Estimate the size of the priority groups that will be vaccinated based on extrapolation from national data or on local data, where available
- Identify locations for vaccination clinics that will be operated by health departments and enter into memoranda of agreement with organizations that agree to provide vaccinators or other staff
- Develop procedures for collecting, removing, and disposing of used syringes, needles, and other vaccination supplies
- Develop a plan for training vaccinators and other staff responsible for mass vaccination
- Develop strategies for vaccinating hard-to-reach populations

State and local health departments' plans should also specifically address the delivery of pandemic vaccine to medically underserved and migrant populations to improve equity in access within priority groups and, later, the general population.

If vaccinations are provided by private-sector organizations or providers at offices, clinics, or other sites, state and local health departments should:

- Develop mechanisms to allocate vaccine based on projected need.
- Develop mechanisms to collect unused vaccine (if any) from healthcare providers who have met their priority vaccination goals and distribute the vaccine to those who have not.
- Provide vaccination information to healthcare providers. This may best be accomplished by developing a communications plan for private-sector vaccine use.
- Monitor that vaccine administration follows existing plans on priority groups.

### a) Second-dose vaccination

A vaccine against pandemic influenza will likely require two doses, administered at least a month apart, to provide a level of immunity comparable to that obtained with seasonal influenza vaccines. Recommendations on the number of required doses and the timing of the second dose will be issued once immunogenicity trials have been completed.

If two doses are required to achieve immunity, it will be necessary to ensure that vaccinated persons return for the second dose. State and local planners should do the following:

- Arrange for information about the need for a second dose to be provided at the time of vaccination.
- Ensure that planning for vaccine procurement and distribution to clinics and other facilities accounts for the need to use portions of future shipments for second doses, thus reducing the number of available first doses.
- Consider implementing a call-back system or immunization registry that would accomplish the goals of pandemic vaccination (see 3.b below).

#### **b) Contingency planning for Investigational New Drug use**

State and local health departments should be prepared to distribute unlicensed vaccines (if needed) under FDA's Investigational New Drug (IND) provisions. Unlicensed vaccines might be needed, for example, if pandemic spread is rapid and standard vaccine efficacy and safety tests are not completed in time to play a role in the response.

IND provisions require strict inventory control and record-keeping, completion of a signed consent form from each vaccinee, and mandatory reporting of specified types of adverse events. IND provisions also require approval from Institutional Review Boards (IRBs) in hospitals, health departments, and other vaccine-distribution venues. The FDA regulations permit the use of a national or "central" IRB. A treatment IND is one IND mechanism that FDA has available for use and is especially suited for large scale use of investigational products ([http://www.access.gpo.gov/nara/cfr/waisidx\\_99/21cfr\\_99.html](http://www.access.gpo.gov/nara/cfr/waisidx_99/21cfr_99.html)).

As an alternative to IND use of an unapproved antiviral drug, HHS may utilize the drug product under Emergency Use Authorization procedures as described in the FDA draft Guidance "Emergency Use Authorization of Medical Products" (<http://www.fda.gov/cber/gdlns/emerase.pdf>).

### **3. Vaccine monitoring and data collection**

To ensure optimal use of a new pandemic influenza vaccine, state and local health departments should be prepared to collect data on vaccine effectiveness, vaccine supply and distribution, vaccine coverage, and vaccine safety.

#### **a) Vaccine effectiveness**

Vaccine effectiveness will be assessed by comparing rates of influenza-related illness, hospitalization, and/or death among vaccinated and unvaccinated persons. These studies will be implemented by CDC in collaboration with healthcare and university partners and with state and local health departments that participate in influenza surveillance systems.

#### **b) Vaccine supply and distribution**

Mechanisms for tracking vaccine supply and distribution will depend on how vaccine is purchased and distributed. Tracking will be implemented by state and local health authorities—who will have major responsibility for allocation decisions—working in association with CDC and vaccine producers. Data also will be obtained from vaccine producers and commercial distributors.

- Vaccine tracking and coverage information may be used by federal, state, and local decision-makers to estimate adverse event rates based on the number of doses administered and to determine if vaccine is being administered according to established priority groups for pandemic vaccine (especially in the early phases of vaccination). Data will be collected from individual providers, collated at the local and state levels, and reported to federal authorities on a scheduled routine basis.

- States with immunization registries may adapt them for use in tracking coverage with pandemic influenza vaccine. Or, states may use a vaccine database that will be supplied by CDC. At a minimum, tracking data should include:
  - Number of doses administered, by date and age, priority group, and state or county (or zip code)
  - Number of doses that represent second doses, as applicable
- State and local authorities may consider additional data requirements for their own needs.

#### c) Vaccine coverage

CDC will work with states to develop a system for monitoring vaccination rates at regular intervals, using a pre-existing population-based survey tool (e.g., Behavioral Risk Factor Surveillance System) that provides national and state-level estimates and complements the vaccine tracking systems described above.

#### d) Vaccine safety

State and local health departments should develop a system to report and investigate adverse events following immunization (AEFI) with a pandemic influenza vaccine. Planning steps might include:

- Designating a state-level coordinator to plan for and implement adverse-events reporting and outreach to and education of providers (e.g., adapting and distributing federally developed Dear Doctor letters and materials for vaccine recipients) and who will serve as the state's contact with federal government staff overseeing the Vaccine Adverse Event and Reporting System (VAERS) ([www.vaers.hhs.gov](http://www.vaers.hhs.gov)).
- Reviewing existing policies for AEFI reporting and follow-up to ensure timeliness of reporting.
- Developing a plan to ensure timely reporting of and communication about large numbers of AEFI reports.
- Reviewing procedures for and familiarizing program staff with the strengths, limitations, and objectives of VAERS. VAERS typically involves direct reporting by individual healthcare providers, with periodic feedback to the states. During a pandemic, some state health departments may wish to receive direct reports of AEFI to conduct investigations of adverse events and minimize duplicate reporting of adverse events to VAERS. State-level AEFI reporting can build on the infrastructure and experience developed during the 2003 smallpox vaccination program.

Adverse events related to use of IND vaccines may be reported through other mechanisms in addition to or in place of VAERS, in accordance with specific regulatory or policy requirements. Adverse events will also be monitored through the Vaccine Safety Datalink ([www.cdc.gov/nip/vacsafe/default.htm#VSD](http://www.cdc.gov/nip/vacsafe/default.htm#VSD)), a network of seven geographically diverse health maintenance organizations through which active surveillance vaccine safety studies are conducted. Another potential resource for vaccine safety research is CDC's Clinical Immunization Safety Assessment (CISA) network ([www.vaccinesafety.org/CISA/index.htm](http://www.vaccinesafety.org/CISA/index.htm)).

### 4. Public health communications

The provision of vaccine information will be an important component of ongoing public health communication during a pandemic (see Supplement 10).

- State and local health departments should work with federal partners to disseminate accurate, useful, and consistent public health messages and should tailor information to local needs as indicated.
- Health departments should provide information to healthcare providers, state and local government officials, and the news media on:
  - Rationale for prioritization and list of priority groups (see Part 1, Appendix D)
  - Phasing of vaccination, if any, after priority groups have been vaccinated
  - When and where vaccination is available

- Importance of vaccination given likelihood of subsequent pandemic waves, particularly if public interest in vaccination has decreased
- As noted above, state and local health departments should be prepared to disseminate information on vaccine use to healthcare providers who purchase private stocks of pandemic influenza vaccine. In addition, all vaccine providers will need vaccine information sheets that describe the risks and benefits of, and contraindications to, vaccination.

## 5. Coordination with bordering jurisdictions

State and local health departments should review and coordinate vaccine distribution plans with health authorities in bordering jurisdictions, including neighboring states, tribal governments and other unique populations.

## 6. Legal preparedness

State and local health departments should ensure that appropriate legal authorities are in place to facilitate implementation of plans for distributing pandemic influenza vaccines. Health departments might undertake these legal preparedness steps:

- Ensure that plans for distribution of vaccines are reviewed by appropriate legal authorities.
- Determine whether state and local laws allow non-licensed volunteers or healthcare workers from other jurisdictions to administer influenza vaccines.
- Work with professional organizations and unions to consider options for emergency performance of tasks outside of standard job descriptions.
- Determine whether state and local laws allow mandatory vaccination to protect public health, if needed.

## 7. Training

State and local health departments can assist healthcare partners in conducting training exercises to facilitate rapid and effective delivery and use of vaccines (see Supplement 3). Exercises and drills are essential to ensure that emergency procedures are in place and that roles and responsibilities are well understood. It may be useful, for example, to practice emergency implementation of mass vaccination (e.g., receiving large quantities of vaccine; storing and handling vaccine; setting up and staffing clinics; administering vaccine; testing information management systems; educating the public, media, and medical providers; targeting specific priority groups).

# S6-IV. RECOMMENDATIONS FOR THE PANDEMIC PERIOD

## A. Before a vaccine is available

Before a vaccine becomes available—state and local health departments should do the following:

- Meet with partners and stakeholders to review the major elements of the state's vaccine distribution plan.
- Modify the plan to account for possible updated interim recommendations on priority groups, projected vaccine supplies and timelines for availability, and staffing estimates for mass vaccination.
- Notify the medical community about the status of the plan and the expected availability of vaccines.
- If stockpiled vaccine of the pandemic subtype is available, work with healthcare partners and other stakeholders to distribute, deliver, and administer vaccines to designated groups.
- Update and disseminate public information on the production, distribution, and use of pandemic influenza vaccine before it becomes available (see Supplement 10).
- Conduct training for public health staff and partners involved in distributing and administering vaccines.

## B. When a vaccine becomes available

- Once a vaccine is ready for distribution, state and local health departments should work with healthcare and community partners to activate plans to:
  - Vaccinate persons in priority groups, in accordance with existing recommendations.
  - Provide a second dose, if required for immunity.
  - Monitor vaccine supply, distribution, and use.
  - Monitor and investigate adverse events.
  - Continue communication with partners and the public.
- After priority groups have been vaccinated and additional vaccine stocks become available, public health authorities should phase-in vaccination of the rest of the population, based on age or other criteria that will ensure fair, equitable, and orderly distribution (see III.B). HHS will issue national recommendations to aid in this process.
- After the pandemic has ended, state and local health departments should evaluate all response activities, including vaccine tracking and delivery, adverse event monitoring, and communications.

## **BOX 1. DEVELOPMENT OF VACCINES AGAINST PANDEMIC STRAINS OF INFLUENZA**

HHS is working with industry partners to ensure that influenza vaccine can be produced on an emergency basis at any time throughout the year (<http://www.HHS.gov/nvpo/pandemicplan/>) and to facilitate the development of cell- and recombinant-based interpandemic and pandemic influenza vaccines towards FDA licensure in U.S.-based manufacturing facilities. Activities in support of these goals include:

- Stimulating expanded manufacturing capacity by increasing annual demand for influenza vaccines by the CMS and CDC
- Securing a year-round egg supply for production of inactivated egg-based influenza vaccines
- Promoting the development of new technologies that:
  - Shorten the time required to develop a vaccine against a new strain of influenza.
  - Facilitate rapid expansion of vaccine production during a pandemic.
  - Optimize the use of limited vaccine supplies (e.g., antigen-sparing strategies).

HHS is also spearheading the development of human vaccines against avian influenza A (H5N1) and against other influenza A viruses with pandemic potential. HHS is providing funding to develop and manufacture pilot investigational lots of these vaccines at licensed influenza vaccine manufacturers and to evaluate their safety and immunogenicity in NIH-sponsored clinical trials in healthy adult, elderly, and pediatric populations.

HHS is acquiring commercial scale lots of influenza A (H5N1) vaccine to provide vaccine manufacturers with experience initially and then to establish and maintain stockpiles of pre-pandemic H5N1 vaccine.



## APPENDIX. RESOURCES FOR MASS VACCINATION AGAINST PANDEMIC INFLUENZA

- **Department of Health and Human Services**
  - Guidelines for large-scale influenza vaccination clinic planning. Developed by CDC's National Immunization Program in response to the 2004 influenza vaccine shortage, this document was prepared to assist in planning for large vaccination clinics. It provides a general overview and guidelines for establishing and running a mass dispensing clinic (<http://www.cdc.gov/flu/professionals/vaccination/pdf/vaxclinicplanning0405.pdf>).
  - Guidelines for large-scale smallpox vaccination clinics. Although this document is specific to smallpox, most of the content is applicable to and can be adapted to other mass vaccination clinics (<http://www.bt.cdc.gov/agent/smallpox/response-plan/files/annex-2.pdf>).
  - Information on Investigational New Drug (IND) use and Emergency Use Authorization (EUA). Regulations governing IND applications are described in 21 CFR 312 ([http://www.access.gpo.gov/nara/cfr/waisidx\\_99/21cfr312\\_99.html](http://www.access.gpo.gov/nara/cfr/waisidx_99/21cfr312_99.html)). Draft guidance for EUA is provided at <http://www.fda.gov/cber/gdlns/emeruse.pdf>.
- **Private-sector partners**
  - Community-based mass prophylaxis: a planning guide for public health preparedness. This report from Cornell University's Weill Medical College describes the five components of a mass prophylaxis/vaccination response to an epidemic (<http://www.ahrq.gov/research/cbmprophyl/cbmpro.htm>).



# **supplement 7** **antiviral drug distribution and use** **TABLE OF CONTENTS**

|                                                                                                                                                         |       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|-------|
| SUMMARY OF PUBLIC HEALTH ROLES AND RESPONSIBILITIES FOR ANTIVIRAL DISTRIBUTION AND USE.....                                                             | S7-2  |
| S7-I. RATIONALE .....                                                                                                                                   | S7-3  |
| S7-II. OVERVIEW .....                                                                                                                                   | S7-4  |
| S7-III. RECOMMENDATIONS FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS.....                                                                           | S7-4  |
| A. Use of antivirals in management of cases of novel influenza .....                                                                                    | S7-4  |
| 1. Use of antivirals for treatment.....                                                                                                                 | S7-4  |
| 2. Use of antivirals for prophylaxis of contacts.....                                                                                                   | S7-5  |
| 3. Use of antivirals for containment of disease clusters.....                                                                                           | S7-5  |
| B. Preparedness planning for use of antivirals during a pandemic.....                                                                                   | S7-5  |
| 1. National recommendations on use of antivirals during a pandemic.....                                                                                 | S7-5  |
| 2. State-level planning .....                                                                                                                           | S7-6  |
| a) Procurement.....                                                                                                                                     | S7-6  |
| b) Establishing priority groups.....                                                                                                                    | S7-7  |
| c) Distributing and dispensing antivirals to priority groups.....                                                                                       | S7-7  |
| d) Monitoring and data collection .....                                                                                                                 | S7-7  |
| (1) Distribution.....                                                                                                                                   | S7-8  |
| (2) Antiviral effectiveness.....                                                                                                                        | S7-8  |
| (3) Adverse events.....                                                                                                                                 | S7-8  |
| (4) Antiviral drug resistance.....                                                                                                                      | S7-8  |
| e) Coordination with bordering jurisdictions .....                                                                                                      | S7-9  |
| f) Legal preparedness.....                                                                                                                              | S7-9  |
| g) Training .....                                                                                                                                       | S7-9  |
| h) Public health information .....                                                                                                                      | S7-9  |
| i) Contingency planning for Investigational New Drug (IND) use.....                                                                                     | S7-10 |
| S7-IV. RECOMMENDATIONS FOR THE PANDEMIC PERIOD .....                                                                                                    | S7-10 |
| A. When pandemic influenza is reported abroad, or sporadic pandemic influenza cases are reported in the United States, without evidence of spread ..... | S7-10 |
| B. When there is limited transmission of pandemic influenza in the United States.....                                                                   | S7-10 |
| C. When there is widespread transmission of pandemic influenza in the United States.....                                                                | S7-11 |
| Box 1. Strategies for Antiviral Use in Pandemic Influenza Treatment and Prophylaxis .....                                                               | S7-12 |
| Box 2. Federal Supplies of Antiviral Drugs in the Strategic National Stockpile (SNS).....                                                               | S7-16 |
| Table 1. Characteristics of Anti-Influenza Antiviral Drugs.....                                                                                         | S7-17 |
| Table 2. Recommended Daily Dosage of Antivirals for Treatment and Prophylaxis.....                                                                      | S7-18 |

## **SUMMARY OF PUBLIC HEALTH ROLES AND RESPONSIBILITIES FOR ANTIVIRAL DISTRIBUTION AND USE**

### **INTERPANDEMIC AND PANDEMIC ALERT PERIODS**

#### **State and local health departments will work with healthcare partners to:**

- Use antivirals in medical management of cases of novel strains of influenza
- Procure and maintain local stockpiles of antiviral drugs
- Develop state-based plans for distribution and use of antiviral drugs during a pandemic

#### **HHS responsibilities:**

- In advance of an influenza pandemic, HHS, in concert with the Congress and in collaboration with the States, will acquire sufficient quantities of antiviral drugs to treat 25% of the U.S. population and, in so doing, stimulate development of expanded domestic production capacity sufficient to accommodate subsequent needs through normal commercial transactions.
- Develop national guidance on use of antivirals during a pandemic, including identification of priority groups for antiviral drug treatment and prophylaxis.
- Continue procurement and maintenance of national supplies of antivirals in the Strategic National Stockpile.
- Maintain a program to test and extend dating of stockpiled antivirals, as needed, based on demonstration of continued potency.
- Develop protocols for monitoring antiviral effectiveness, safety, and resistance during a pandemic.
- Develop and distribute communication and education materials about antivirals for use by states and other stakeholders.

### **PANDEMIC PERIOD**

#### **State and local health departments will work with healthcare partners to:**

- Prepare to activate state-based plans for distributing and administering antivirals to persons in priority groups.
- Review modifications, if any, to interim recommendations on antiviral prophylaxis in selected groups or circumstances.
- Accelerate training on appropriate use of antiviral drugs among public health staff and healthcare partners.
- Work with other governmental agencies and non-governmental organizations to ensure effective public health communications.

#### **HHS responsibilities:**

- Revise recommendations for treatment and prophylaxis with antivirals for priority groups, if necessary, guided by accumulating data about the pandemic virus (e.g., susceptibility, virulence, transmissibility, geographic spread, and age-specific attack rates).
- Provide state, territorial and local health departments, and healthcare partners with guidance on reporting specifications for tracking distribution, effectiveness, and safety of antivirals.

## PANDEMIC PERIOD (CONT.)

- Work with WHO and global partners to determine the drug susceptibilities of the pandemic strain and monitor changes over time.
- Provide state, territorial and local health departments, and healthcare partners with guidance on reporting specifications for tracking distribution, effectiveness, and safety of antivirals.
- Provide information to health professionals and the public on issues related to availability and use of antiviral drugs during an influenza pandemic.

### If pandemic influenza is detected in the United States:

State and local health departments will work with healthcare partners to:

- Distribute and deliver stockpiled supplies of antivirals, as appropriate, to healthcare facilities that will administer them to priority groups.
- Work with HHS to monitor antiviral drug use and effectiveness.
- Work with HHS to monitor and investigate adverse events.
- Provide updated information to the public via the news media.

### Federal responsibilities:

- Establish and maintain stockpiles of influenza antiviral drugs at the SNS.
- Distribute antiviral drugs from the SNS to state and large city health departments and federal agencies with direct patient care responsibilities, as appropriate.
- Work with state and local health departments and healthcare partners to:
  - Evaluate the effectiveness of antivirals for treatment and prophylaxis.
  - Monitor the incidence of adverse events associated with antiviral use.
  - Monitor the emergence of antiviral resistance.
- Issue updated national guidelines for appropriate use of antivirals as the pandemic continues.
- Continue to provide information to health professionals and the public, as the situation changes, on drug availability, distribution, administration, side effects, and the rationale for targeted drug use.

## S7-I. RATIONALE

Drugs with activity against influenza viruses ("antivirals") include the adamantanes *amantadine* and *rimantadine* and the neuraminidase inhibitors *oseltamivir* and *zanamivir* (see Table 1 and Appendix). Appropriate use of these agents during an influenza pandemic may reduce morbidity and mortality and diminish the overwhelming demands that will be placed on the healthcare system. Antivirals might also be used during the Pandemic Alert Period in limited attempts to contain small disease clusters and potentially slow the spread of novel influenza viruses. A huge and uncoordinated demand for antivirals early in a pandemic could rapidly deplete national and local supplies. Preparedness planning for optimal use of antiviral stocks is therefore essential.

## S7-II. OVERVIEW

Supplement 7 provides recommendations to state and local partners on the distribution and use of antiviral drugs for treatment and prophylaxis during an influenza pandemic. The Interpandemic and Pandemic Alert Period recommendations focus on preparedness planning for the rapid distribution and use of antiviral drugs (e.g., procurement, distribution to priority groups, legal preparedness, training, and data collection on use, effectiveness, safety, and the development of drug resistance). These recommendations also cover the use of antiviral drugs in the management and containment of cases and clusters of infection with novel strains of influenza, including avian influenza A (H5N1) and human strains with pandemic potential.

The Pandemic Period recommendations focus on the local use of antiviral drugs in three situations: 1) when pandemic influenza is sporadically reported in the United States (without evidence of spread in the United States), 2) when there is limited transmission of pandemic influenza in the United States, and 3) when there is widespread transmission in the United States. National recommendations for optimal use of limited stocks of antivirals will be updated throughout the course of an influenza pandemic to reflect new epidemiologic and laboratory data. Interim recommendations will also be updated as an effective influenza vaccine becomes available.

The activities described below are primarily the responsibility of government health authorities at the state, federal, and local levels. Additional issues that may be of interest to healthcare partners who administer antiviral drugs are outlined in Supplement 3.

## S7-III. RECOMMENDATIONS FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS

### A. Use of antivirals in management of cases of novel influenza

Influenza infections may be due to:

- 1) Interpandemic (i.e., 'normal') seasonal strains of influenza<sup>1</sup>
- 2) Novel strains of influenza that do not appear to be easily transmissible but could be precursors to human pandemic strains (e.g., avian influenza A [H5N1] viruses)
- 3) Novel strains of influenza that demonstrate person-to-person transmission and therefore have pandemic potential (e.g., a new human pandemic strain)

In this document the term "novel strains of influenza" is used to refer to avian or animal influenza strains that can infect humans (like avian influenza A [H5N1]) and new or re-emergent human influenza viruses that cause cases or clusters of human disease. Criteria for early detection and identification of novel strains of influenza are discussed in Supplement 1.

#### 1. Use of antivirals for treatment

A patient with a suspected case of avian influenza A (H5N1) or another novel strain of influenza should be isolated as described in Supplement 4 and treated in accordance with the clinical algorithm for the Pandemic Alert Period provided in Supplement 5. As of fall 2005, the recommendation for treatment includes the use of oseltamivir or zanamivir, administered as early as possible and ideally within 48 hours after onset of symptoms. These neuraminidase inhibitors are preferred because the majority of avian influenza A (H5N1) viruses currently affecting humans are resistant to amantadine and rimantadine, and resistance to these drugs typically develops rapidly when they are used for treatment of influenza. Although resistance to

<sup>1</sup> Information on seasonal outbreaks of interpandemic influenza, including public health measures to contain outbreaks, can be found at <http://www.cdc.gov/flu/>.

zanamivir and oseltamivir can be induced in influenza A and B viruses *in vitro*, multiple passages in cell culture are usually required to produce neuraminidase inhibitor resistance, in contrast with adamantane resistance, which can develop after a single passage.<sup>2,3</sup> Because the neuraminidase inhibitors have different binding sites for the enzyme, cross-resistance between zanamivir- and oseltamivir-resistant viruses is variable. Current U.S. recommended doses for antiviral treatment are provided in Table 2.

## 2. Use of antivirals for prophylaxis of contacts

State and local health departments, in consultation with CDC, will consider whether it is necessary and feasible to trace a patient's close contacts and provide them with postexposure antiviral prophylaxis.

Close contacts may include family, schoolmates, workmates, healthcare providers, and fellow passengers if the patient has been traveling. If deemed necessary by public health authorities, these persons may receive post-exposure prophylaxis with oseltamivir, as zanamivir is not currently indicated for prophylaxis. If the exposure to the novel influenza virus strain occurs during the regular influenza season, the patient's healthcare contacts (who may also care for persons with seasonal influenza) should be vaccinated against seasonal influenza to reduce the possible risk of co-infection and reassortment of seasonal and novel strains.

## 3. Use of antivirals for containment of disease clusters

In special circumstances, state and local health departments could consider "targeted antiviral prophylaxis" as a community-based measure for containing small clusters of infection with novel strains of influenza (see **Supplement 8**). This measure could be implemented in small, well-defined settings such as the initial introduction of a virus with pandemic potential into a small community or a military base. However, once a pandemic is underway, such a strategy would not represent an efficient use of limited antiviral supplies.

Because targeted antiviral prophylaxis would require rapid delivery and administration of substantial stocks of antiviral drugs, its feasibility should be evaluated in light of antiviral drug supply and interim recommendations on antiviral drug use during a pandemic (see S7-III.B). Targeted antiviral prophylaxis would involve investigation of disease clusters, administration of antiviral treatment to persons with confirmed or suspected cases of pandemic influenza, and provision of drug prophylaxis to all persons in the affected community. Targeted antiviral prophylaxis would also require intensive case-finding in the affected area as well as effective communication with the affected community.

# B. Preparedness planning for use of antivirals during a pandemic

## 1. National recommendations on use of antivirals during a pandemic

HHS is working with private-sector partners to increase production of antivirals and to procure additional stocks of antivirals for the Strategic National Stockpile (SNS) (<http://www.HHS.gov/nvpo/pandemicplan/>). Despite these efforts, demand for antivirals during an influenza pandemic is likely to far outstrip supplies available in stockpiles or through usual channels of distribution.

- A list of priority groups for receiving antiviral treatment or prophylaxis and the rationale for prioritization are provided in Part 1 Appendix D. During an actual pandemic, these recommendations could be modified, based on the characteristics of the causative virus (e.g., drug susceptibilities, initial geographic distribution, fatality rate, age-specific morbidity and mortality rates) and the effectiveness of implemented strategies.

2 McKimm-Breschkin JL. Resistance of influenza viruses to neuraminidase inhibitors — a review. *Antiviral Res.* 2000; 47:1-17.

<sup>3</sup> Tisdale M. Monitoring of viral susceptibility: new challenges with the development of influenza NA inhibitors. *Rev Med Virol*, 2000, 10:45-55.

## 2. State-level planning

State and local health departments should work with healthcare partners to develop state-based plans for antiviral need, procurement, distribution, and targeted use. Materials of potential benefit in these efforts include:

- Strategies outlined in Box 1 for optimizing antiviral use in treatment and prophylaxis. These strategies are based on scientific findings summarized in the July 2005 recommendations of the Advisory Committee on Immunization Practices (ACIP). <http://www.cdc.gov/mmwr/PDF/rr/rr5408.pdf>
- Clinical treatment algorithms provided in **Supplement 5**
- Interim recommendations developed by NVAC on priority groups for prophylaxis and treatment (see Part 1, Appendix D)
- Existing plans for emergency distribution of medical supplies (e.g., bioterrorism plans or SARS plans)

State-based planning for antiviral use should include obtaining antiviral drugs from national, state, and local stockpiles, and their distribution to priority groups by healthcare providers; data collection on drug use, drug-related adverse events, and drug resistance; coordination with bordering jurisdictions; legal preparedness; training; and dissemination of public health information.

These planning efforts require coordination and collaboration with healthcare providers who will administer antivirals during a pandemic. Examples of collaborative planning activities include:

- Convening local or state-wide pandemic influenza strategy meetings on the use of antivirals to facilitate local planning and define public- and private-sector roles (e.g., related to rapid administration to priority groups and medical surge capacity)
- Involving the local medical community (critical care, infectious disease, emergency medicine, and other specialties) in refining national guidelines for treatment and prophylaxis and providing information to the media and local populations on the appropriate use of antivirals
- Identifying contacts in tribal authorities and bordering states for coordinating distribution of antivirals (see below)

### a) Procurement

Examples of planning steps for state-level procurement of antivirals include:

- Estimating the quantities of antiviral drugs that will be needed for treatment and prophylaxis of priority groups (see below)
- Identifying sources of antiviral drugs (e.g., state stockpiles, private sector, and federal supplies from the SNS). Drug procurement strategies might include:
  - Creating state or local stockpiles
  - Encouraging healthcare facilities to create institutional stockpiles
  - Making arrangements with local private-sector distributors for emergency purchase of antiviral drugs, if available

The establishment of state, local, or institutional stockpiles should take into account the expiration dates of the purchased material. All drugs are marked with an expiration date, based on review of stability data, at the time of manufacture. However, when purchased, the drugs might have been stored for some time in warehouses so that the time to expiration might be shorter than the time from initial manufacture to expiration date. Moreover, one shipment might consist of several batches with different expiration dates. Antivirals maintained in the national stockpile may be tested for potency and dating extended under the FDA shelf life extension program. Currently, state stockpiles are not included in this program.



#### **b) Establishing priority groups**

Based on interim recommendations on priority groups for antiviral treatment and prophylaxis (see Part 1, Appendix D), state and local health authorities should determine how certain priority groups (e.g., public safety workers, essential service providers, key decision makers) will be defined in their jurisdictions.

The Department of Defense (DoD) has purchased a supply of antivirals for use during a pandemic. Should the pandemic occur before the stockpile is received, DoD may require a portion of the national stockpile to treat or protect personnel in order to continue current combat operations and to preserve critical components of the military medical system. Should the military stockpile be exhausted and additional antiviral medication required to ensure national defense or continued support to civil authorities, use of antiviral drugs from the national stockpile may also be required.

#### **c) Distributing and dispensing antivirals to priority groups**

Planning steps for distribution of antivirals to priority groups might include:

- Estimating the size and needs of priority groups in local jurisdictions, using interim recommendations
- Assessing antiviral stocks available at the state, local, and hospital levels
- Establishing a mechanism to request antivirals from the federal stockpile, if needed (see below)
- Activating pre-existing plans for the transport, receipt, storage, security, tracking, and delivery of:
  - Antiviral stocks for use in treatment to hospitals, clinics, nursing homes, alternative care facilities, and other healthcare institutions. Prompt dispensing to point-of-care locations is crucial, because clinical efficacy for these agents has been demonstrated when treatment begins within 48 hours of the onset of symptoms.
  - Antiviral stocks for use in post-exposure prophylaxis (e.g., for direct contacts of infected patients)
  - Antiviral stocks for use in prophylaxis (e.g., if recommended for healthcare workers, public safety workers, and essential service providers)
- Considering the use of standing orders for treatment of certain priority groups, such as hospitalized patients and healthcare workers
- Developing a communication plan to explain the rationale for establishing these target groups (see also **Supplement 10**)

The decision to deploy federal assets from the SNS during an influenza pandemic will be made by HHS officials, as it would be during any public health emergency. Each state and federal agency with direct patient care responsibilities should designate a representative (e.g., the state epidemiologist or public health director) to make emergency requests for federal assets in the SNS.

Federal supplies of antivirals will be delivered to a site designated by state planners in each state or large city (e.g., state health department; existing SNS receipt, storage, staging site). State SNS coordinators should provide logistical guidance on the receipt and distribution of federal assets to priority groups.

#### **d) Monitoring and data collection**

To ensure optimal use of antiviral drugs during an influenza pandemic, state and local health departments and healthcare partners should work with federal officials and collect data on:

- Distribution of state or federal supplies of antiviral drugs
- Occurrence of adverse events following administration of antiviral drugs

State and local departments could also participate in federal efforts to collect data on:

- Effectiveness of treatment and prophylaxis
- Development of drug resistance

**(1) Distribution.** Allocation and distribution of antiviral drugs from state and local health departments to drug delivery or dispensing sites will be established based on state and local pandemic plans. Health departments should develop strategies to monitor drug distribution and use, assessing whether drugs are being effectively targeted to priority groups and whether distribution is equitable within those groups (e.g., among racial and ethnic minorities and persons of different socioeconomic levels).

**(2) Antiviral effectiveness.** Studies to evaluate the effectiveness of antiviral drug use during a pandemic will be conducted by federal agencies in collaboration with state and local health departments and other healthcare and academic partners. The effectiveness of antiviral therapy and prophylaxis will be assessed by comparing rates of severe influenza-related illness and death among treated and untreated persons and among persons who did and did not receive prophylaxis. Analyses of antiviral drug effectiveness should take into account characteristics that will vary among individuals and those that may vary over time, such as diagnostic practices, length of time to initiate therapy, and changes in the pandemic virus.

**(3) Adverse events.** Serious adverse events associated with the use of antiviral drugs for prophylaxis and treatment of influenza should be reported to FDA, using the MedWatch monitoring program. During an influenza pandemic, state and local health departments can assist in this effort by providing protocols and information to healthcare providers and encouraging hospitals to download MedWatch forms (available at <http://www.fda.gov/medwatch/>) for distribution to patients. Adverse events reported to MedWatch are collated and analyzed by FDA's Adverse Events Reporting System (AERS).

Use of antivirals will be much greater during a pandemic than during a regular influenza season.. To help improve the detection of serious adverse effects (especially rare effects or effects in vulnerable populations), additional efforts to encourage recognition and reporting of adverse events will be needed. These efforts might include:

- Active monitoring for adverse events observed at emergency rooms, through the National Electronic Injury Surveillance System Cooperative Adverse Drug Event project (NEISS-CADE)
- Local campaigns to educate healthcare workers about the recognition and reporting of adverse events
- Distribution of MedWatch forms and descriptions of known adverse events to each end-user who receives antiviral drugs

In addition, CDC, FDA, and AHRQ will explore the use of existing drug-monitoring systems that have access to individual health utilization records that may allow active, population-based surveillance for adverse events following the use of antivirals for treatment or prophylaxis.

**(4) Antiviral drug resistance.** CDC will work with state and local partners to monitor the development of resistance to antivirals. Because resistance to M2 inhibitors may involve a single base pair change, resistance may develop rapidly if these drugs are used widely. Information about resistance to M2 inhibitors and neuraminidase inhibitors can be found in the July 2005 recommendations of the ACIP <http://www.cdc.gov/mmwr/PDF/rr/rr5408.pdf>.

Global surveillance for neuraminidase resistance during a pandemic will also be conducted by the Neuraminidase Inhibitor Susceptibility Network (NISN). The global NISN was established in 1999 to address public health and regulatory concerns regarding the potential emergence and consequences of drug resistance in influenza viruses following the introduction of the influenza neuraminidase inhibitor (NI) class of antiviral agents. The Network includes representatives of each of the four WHO global influenza reference laboratories and scientists from regions of the world where increasing use of these drugs is anticipated.

CDC will test the drug susceptibilities of viruses isolated from different age groups and geographic groups over the course of the pandemic (see Antiviral Effectiveness above). State and local health departments should encourage clinicians to obtain specimens from patients who develop severe disease while receiving treatment or prophylaxis. State health departments should provide these specimens on a periodic basis, preferably after testing them by RT-PCR, viral culture, or rapid diagnostic testing to confirm the presence of strains of influenza A (see Supplement 2).

Surveillance for antiviral resistance may be particularly important during the later stages of the pandemic, especially if M2 agents have been widely used. Under these circumstances, the detection of widespread M2 inhibitor resistance might require a re-evaluation of priorities for prophylaxis and treatment.

#### **e) Coordination with bordering jurisdictions**

State and local health departments should review and coordinate antiviral drug distribution plans with health authorities in bordering jurisdictions, including:

- Counties
- States
- Tribal governments and other unique populations

During an influenza pandemic, states should share details regarding their distribution of antivirals with bordering jurisdictions to optimize targeting of antiviral use and clarify, in advance, any apparent inconsistencies in proposed policies.

#### **f) Legal preparedness**

State and local health departments should ensure that appropriate legal authorities are in place to facilitate implementation of plans for distributing antivirals. For example, if a state plan includes a provision for the state health commissioner to issue a blanket prescription for dispensing of antivirals, then the state health officer will need the authority and the plan will need to be consistent with state prescription laws. In addition, legal issues may include reviewing worker's compensation laws to determine how they apply to healthcare workers and other essential workers who take antivirals for prophylaxis.

#### **g) Training**

State and local health departments should enhance training and education efforts related to use of antiviral drugs during a pandemic. Exercises that involve healthcare providers who will administer antivirals to individual patients are essential to ensure that distribution systems are in place and that roles and responsibilities are well understood. It may be useful, for example, to provide healthcare providers with educational materials and to practice emergency distribution of antiviral drugs to target groups.

#### **h) Public health information**

State and local health departments should develop and implement plans to educate the public, the medical community, and other stakeholders about:

- Role of antivirals in responding to pandemic influenza
- Need to prioritize use of limited antiviral supplies for treatment and prophylaxis
- Rationale for the priority groups identified in the interim recommendations
- Importance of appropriate use (i.e., using the drugs as prescribed and for the full number of days recommended) to minimize the development of drug resistance

#### i) Contingency planning for Investigational New Drug (IND) use

State and local health departments should be prepared to distribute unlicensed antiviral drugs (if needed) under FDA's Investigational New Drug (IND) provisions. IND provisions require strict inventory control and recordkeeping, completion of a signed consent form from each person who receives the medication, and mandatory reporting of specified types of adverse events. IND provisions also require approval of the protocol and consent form by an Institutional Review Board (IRB). The FDA regulations permit the use of a national or "central" IRB. A treatment IND is one IND mechanism that FDA has available for use and is especially suited for large scale use of investigational products. [http://www.access.gpo.gov/nara/cfr/waisidx\\_99/21cfr\\_99.html](http://www.access.gpo.gov/nara/cfr/waisidx_99/21cfr_99.html)

As an alternative to IND use of an unapproved antiviral drug, HHS may utilize the drug product under Emergency Use Authorization procedures as described in the FDA draft Guidance "Emergency Use Authorization of Medical Products" <http://www.fda.gov/cber/gdlns/emerguse.pdf>

### S7-IV. Recommendations for the Pandemic Period

Interim recommendations for use of antivirals may be updated throughout the course of an influenza pandemic to reflect current epidemiologic and laboratory data. Interim recommendations may also be updated as an effective influenza vaccine becomes available.

#### A. When pandemic influenza is reported abroad, or sporadic pandemic influenza cases are reported in the United States, without evidence of spread

If an influenza pandemic has begun in other countries, state and local health departments should:

- Use antiviral drugs in the management of persons infected with novel strains of influenza and their contacts, as described in S7-III.A or its updates.
- Work with healthcare partners to consider providing antiviral prophylaxis to persons at highest risk for pandemic influenza. Examples of such persons include:
  - Public health workers who investigate suspected cases of pandemic influenza
- Meet with local partners and stakeholders to review the state-based antiviral drug distribution plan (see S7-III.B). As part of this effort, state and local partners could:
  - Modify the distribution plan to take into account possible updated recommendations on target groups and updated information on projected supplies of antiviral drugs.
  - Notify the medical community about the status of the plan and the availability of antiviral drugs.
  - Disseminate public health guidelines that encourage drug-use practices that help minimize the development of drug resistance.
  - Provide the public with information on interim recommendations and their rationale for the use of antiviral drugs during an influenza pandemic.
- Work with federal partners to monitor the safety and effectiveness of drugs and ensure that available antivirals are used in accordance with federal and local recommendations.

#### B. When there is limited transmission of pandemic influenza in the United States

When there is limited transmission of pandemic influenza in the United States, state and local health departments should:

- Activate state-based plans for targeting antiviral drugs to priority groups for prophylaxis and treatment (see S7-III.B).

- Request antiviral drugs, as needed, from previously identified sources (see S7-III.B), including the SNS.
- Continue to work with healthcare partners to ensure appropriate use of antivirals in the medical management of early cases and contacts (see S7-IV.A).
- Assist hospitals in implementing procedures for early detection and treatment of influenza in healthcare workers (see Supplement 3).
- Work with federal partners to begin monitoring the safety and effectiveness of drugs and ensure that available antivirals are used in accordance with federal and local recommendations.

## **C. When there is widespread transmission of pandemic influenza in the United States**

When transmission of pandemic influenza has become widespread, the paramount goals of antiviral use will be to treat those at highest risk of severe illness and death and to preserve the delivery of healthcare and other essential critical services through early treatment and limited prophylaxis.

After a vaccine becomes available, antiviral drugs may be used to protect persons who have an inadequate vaccine response (e.g., the elderly and those with underlying immunosuppressive disease) as well as persons with contraindications to vaccination, such as anaphylactic hypersensitivity to eggs or other vaccine components.

Until the pandemic has waned, state and local health departments should continue to work with healthcare and federal partners to monitor the safety and effectiveness of antivirals and to encourage appropriate drug use practices that help minimize the development of drug resistance.

## **BOX 1. STRATEGIES FOR ANTIVIRAL USE IN PANDEMIC INFLUENZA TREATMENT AND PROPHYLAXIS**

The goals of vaccine and antiviral use during an influenza pandemic are to limit mortality and morbidity, minimize social disruption, and reduce economic impact. Because a pandemic vaccine is unlikely to be available during the first 4 to 6 months of the pandemic, appropriate use of antivirals may play an important role in achieving these goals.

### **A. Treatment**

#### **1. Planning considerations**

- The effectiveness of antivirals against a new pandemic influenza virus cannot be predicted.
- Pooled analyses of clinical trials of neuraminidase inhibitors administered to outpatients with seasonal influenza suggest that early treatment may reduce the risk of hospitalization by ~50%. There are no data on the effectiveness of neuraminidase inhibitors in preventing either serious morbidity (e.g., requirement for intensive care) or mortality (see July 2005 recommendations of the AHIC (<http://www.cdc.gov/mmwr/PDF/rr/rr5408.pdf>)).
- Antiviral agents used against seasonal influenza have demonstrated efficacy in clinical trials when treatment is initiated within 48 hours of the onset of symptoms. Assuming that they have a similar level of effectiveness against pandemic influenza, rapid diagnosis, distribution and administration of antivirals during a pandemic will be essential.
- Early treatment is a more efficient use of antivirals than widespread prophylaxis. Because prophylaxis for approximately 6 weeks would require at least four times the number of doses as a 5-day treatment course per individual, huge antiviral stockpiles would be required to permit prophylaxis of more than a small proportion of the U.S. population.
- Most influenza A(H5N1) viruses currently in circulation in southeast Asia are resistant to the M2 ion channel inhibitors (amantadine and rimantadine), and strains that may evolve from these viruses may become resistant to this class of antivirals.

The emergence of drug resistant strains is less likely during treatment with neuraminidase inhibitors (oseltamivir and zanamivir) than with M2 inhibitors (amantadine and rimantadine). Neuraminidase inhibitors may also have a lower incidence of severe side effects (see July 2005 recommendations of the AHIC (<http://www.cdc.gov/mmwr/PDF/rr/rr5408.pdf>)). Oseltamivir and zanamivir should therefore be reserved for treatment whenever possible. Because supplies of oseltamivir and zanamivir are currently depleted, early depletion of oseltamivir and widespread use of M2 inhibitors could lead to increased rates of side effects and drug resistance.

#### **2. Strategies for treatment**

Treatment strategies for optimizing the use of limited stocks of antiviral drugs will vary depending on the phase of the pandemic. The following interim guidance will be updated as more information becomes available. Strategies for consideration include:

##### **At all stages of a pandemic:**

- Targeting therapy to influenza patients admitted to a hospital who present within 48 hours of symptom onset.
- Implementing mechanisms to detect the emergence of drug-resistant variants of a pandemic influenza strain (e.g., obtaining specimens from persons who develop influenza while on prophylaxis or who progress to severe disease despite treatment).

## **BOX 1. STRATEGIES FOR ANTIVIRAL USE IN PANDEMIC INFLUENZA TREATMENT AND PROPHYLAXIS (CONT.)**

### **During the earliest stages of a pandemic in the United States:**

- Basing treatment decisions on laboratory-confirmed subtype identification of the pandemic strain by viral isolation, RT-PCR, or other means recommended by CDC. A positive rapid antigen test for influenza A would be sufficient grounds for initiating treatment, with a confirmatory, definitive laboratory test required for continuation of treatment.
- Interpreting negative results of influenza testing as permitting termination of treatment, given the overall low rate of infection in a particular community.
- Considering targeted use of antivirals to contain small, well-defined disease clusters, to possibly delay or reduce spread to other communities (see also Part C [below] and Supplement 8).

### **When there is increasing disease activity in the United States:**

- Basing treatment decisions on:
  - Laboratory-confirmed identification of the pandemic subtype by viral isolation and subtyping, RT-PCR, or other means recommended by CDC, *or*
  - Detection of influenza A by rapid antigen test, *or*
  - Epidemiologic and clinical characteristics.
- Permitting initiation of antiviral treatment before results from viral isolation, IFA, RT-PCR assays, or rapid antigen tests become available, since early treatment is more likely to be effective.

Once infection becomes more common, negative rapid antigen test results are more likely to represent false negatives; therefore, treatment should continue while awaiting results from confirmatory testing.

### **When the pandemic is widespread in the United States:**

- Basing treatment decisions on clinical features and epidemiologic risk factors, taking into account updated knowledge of the epidemiology of the pandemic virus.

As the pandemic progresses, strategies for antiviral treatment may be revised as new information is obtained about the pandemic strain.

## **B. Prophylaxis**

### **1. Planning considerations for prophylaxis**

- Primary constraints on the use of antivirals for prophylaxis will be:
  - Limited supplies
  - Increasing risk of side effects with prolonged use
  - Potential emergence of drug-resistant variants of the pandemic strain, particularly with long-term use of M2 inhibitors
- The need for antiviral prophylaxis may decrease once an effective pandemic influenza vaccine becomes available for use among healthcare workers and other groups receiving prophylactic antivirals.



## **BOX 1. STRATEGIES FOR ANTIVIRAL USE IN PANDEMIC INFLUENZA TREATMENT AND PROPHYLAXIS (CONT.)**

- Post-exposure prophylaxis might be useful in attempts to control small, well-defined disease clusters (e.g., outbreaks in long-term care facilities [see section C below]). A study of post-exposure prophylaxis using amantadine—conducted during the 1968 pandemic—demonstrated little effectiveness, possibly due to rapid development of resistance (see July 2005 recommendations of the AHIC (<http://www.cdc.gov/mmwr/PDF/rr/rr5408.pdf>)).
- Oseltamivir has demonstrated >70% efficacy as prophylaxis against laboratory-confirmed febrile influenza illness during interpandemic periods in unimmunized adults (see July 2005 recommendations of the AHIC (<http://www.cdc.gov/mmwr/PDF/rr/rr5408.pdf>)).
- Prophylaxis with amantadine or rimantadine decreased the risk of influenza illness during the 1968 pandemic and the 1977 reappearance of H1N1 viruses (see July 2005 recommendations of the AHIC (<http://www.cdc.gov/mmwr/PDF/rr/rr5408.pdf>)).
- The number of persons who receive prophylaxis with oseltamivir should be minimized, primarily to extend supplies available to treat persons at highest risk of serious morbidity and mortality. If sufficient antiviral supplies are available, prophylaxis should be used only during peak periods of viral circulation to protect small groups of front-line healthcare workers and other providers of essential community services prior to availability of vaccine.
- If a pandemic virus is susceptible to M2 ion channel inhibitors, amantadine and rimantadine should be reserved for prophylaxis, although drug resistance may emerge quickly.
- Rimantadine is preferred over amantadine, because it is associated with a lower incidence of serious side effects (see July 2005 recommendations of the AHIC (<http://www.cdc.gov/mmwr/PDF/rr/rr5408.pdf>)). Strains that are resistant to one M2-class antiviral are likely resistant to the other.

## **2. Strategies for prophylaxis**

Strategies for effective use of antiviral prophylaxis during a pandemic include:

- Targeting prophylaxis to priority groups (see Part 1, Appendix D for interim recommendations) throughout the first wave of the pandemic. Data from 20th century influenza pandemics suggest that the first wave of these pandemics lasted approximately 4 to 8 weeks in a community.
- Using post-exposure prophylaxis (generally for 10 days) to:
  - Control small, well-defined disease clusters, such as outbreaks in nursing homes or other institutions, to delay or reduce transmission to other communities (see part C above).
  - Protect individuals with a known recent exposure to a pandemic virus (e.g., household contacts of pandemic influenza patients).

When a vaccine becomes available, post-exposure prophylaxis may also be used to protect key personnel during the period between vaccination and the development of immunity.

Strategies for antiviral prophylaxis may be revised as the pandemic progresses, depending on supplies, on what is learned about the pandemic strain and on when a vaccine becomes available.

## **BOX 1. STRATEGIES FOR ANTIVIRAL USE IN PANDEMIC INFLUENZA TREATMENT AND PROPHYLAXIS (CONT.)**

### **C. Strategies for Combined Treatment and Prophylaxis**

During the Pandemic Alert Period, combined antiviral treatment for ill persons and targeted post-exposure prophylaxis of contacts might be considered in attempts to contain small disease clusters (e.g., institutional outbreaks or household introductions). The potential use of targeted prophylaxis to contain disease clusters is considered in **Supplement 8**.

The administration of oseltamivir does not interfere with the development of antibodies to influenza viruses after administration of trivalent inactivated influenza vaccine. Therefore, persons receiving prophylaxis can continue to receive oseltamivir during the period between vaccination and the development of immunity. Whether oseltamivir can interfere with the immune response elicited by a live-attenuated pandemic vaccine is unknown.

### **D. Pediatric Use**

None of the available influenza antivirals are currently FDA approved for use among children aged <1 year. In particular, the safety and efficacy of oseltamivir have not been studied in children aged <1 year for either treatment or prophylaxis of influenza (see oseltamivir package insert). The decision by an individual physician to treat children aged <1 year in an emergency setting on an off-label basis with an antiviral must be made on a case-by-case basis with full consideration of the potential risks and benefits. Additional human data on the safety of these agents in the treatment of influenza in young children are needed.

Oseltamivir is available as an oral suspension for use in children. This formulation of oseltamivir may not be available in sufficient supply during a pandemic to treat all pediatric patients. If physicians consider opening 75 mg oseltamivir capsules and using the contents in an attempt to deliver a partial, pediatric dose to children, it must be recognized that there are insufficient data on palatability, stability, and dosing consistency to predict the safety or effectiveness of such unapproved use. Additional study of these issues is needed.

## **BOX 2. FEDERAL SUPPLIES OF ANTIVIRAL DRUGS IN THE STRATEGIC NATIONAL STOCKPILE**

During an influenza pandemic, a decision to deploy federal assets from the Strategic National Stockpile (SNS) will be made by HHS. As of October 2005, the SNS (<http://www.bt.cdc.gov/stockpile/>) contained 2.26 million treatment regimens of oseltamivir (capsules and suspension), 5 million treatment regimens of rimantadine (tablets and syrup), and 84,000 treatment regimens of zanamivir. Two million additional oseltamivir courses will be delivered to the SNS by November 2005 and additional purchases of antivirals are pending.

The details of the HHS approach for allocation and distribution of SNS assets during an influenza pandemic are currently under consideration. State and local health departments and federal agencies with direct patient care responsibilities should begin to:

- Develop plans to allot antivirals to healthcare facilities, assuming that distribution of limited supplies of antivirals will initially be targeted to patients hospitalized with pandemic influenza and for treatment or prophylaxis of essential healthcare workers.
- Consider the use of standing orders for the prescription of antivirals, particularly for use in healthcare workers.
- Consider the use of occupational health clinics in hospitals and other healthcare organizations for delivery of antivirals to healthcare workers.

It is not recommended that individuals, fearing a pandemic, stockpile oseltamivir in homes or that healthcare providers prescribe oseltamivir to individuals for prophylaxis against pandemic influenza. At the present time, quantities are insufficient to address all of the interim pre-determined groups, and thus stockpiling oseltamivir will take away limited resources from those with highest priority.

**TABLE 1. CHARACTERISTICS OF ANTI-INFLUENZA ANTIVIRAL DRUGS**

|             | Inhibits       | Acts on           | Administration | Common Side Effects                  |
|-------------|----------------|-------------------|----------------|--------------------------------------|
| Amantadine  | M2 ion channel | Influenza A       | Oral           | CNS, GI                              |
| Rimantadine | M2 ion channel | Influenza A       | Oral           | CNS, GI (less often than amantadine) |
| Oseltamivir | Neuraminidase  | Influenza A and B | Oral           | GI                                   |
| Zanamivir   | Neuraminidase  | Influenza A and B | Inhaler        | Bronchospasm                         |

These agents differ in mechanisms of action, pharmacokinetics, FDA-approved indications, dosages, cost, and potential for emergence of drug resistance (see July 2005 recommendations of the AHIC (<http://www.cdc.gov/mmwr/PDF/rr/rr5408.pdf>)).

The neuraminidase inhibitors and rimantadine are superior to amantadine with regard to the frequency of serious side effects.

The use of M2 inhibitors, particularly for treatment, is likely to lead to the emergence and spread of drug-resistant influenza viruses.

**TABLE 2. RECOMMENDED DAILY DOSAGE OF ANTIVIRALS FOR TREATMENT AND PROPHYLAXIS**

(From *Prevention and Control of Influenza Recommendations of the Advisory Committee on Immunization Practices [ACIP], July 2005*)

| Antiviral Agent                           | Age Groups (years)                                                     |                                                                        |                                            |                                   |                         |
|-------------------------------------------|------------------------------------------------------------------------|------------------------------------------------------------------------|--------------------------------------------|-----------------------------------|-------------------------|
|                                           | 1–6                                                                    | 7–9                                                                    | 10–12                                      | 13–64                             | ≥65                     |
| <b>Amantadine<sup>a</sup></b>             |                                                                        |                                                                        |                                            |                                   |                         |
| Treatment, influenza A                    | 5mg/kg body weight/day up to 150 mg in two divided doses <sup>b</sup>  | 5mg/kg body weight /day up to 150 mg in two divided doses <sup>b</sup> | 100 mg twice daily <sup>c</sup>            | 100 mg twice daily <sup>c</sup>   | ≤100 mg/day             |
| Prophylaxis, influenza A                  | 5mg/kg body weight /day up to 150 mg in two divided doses <sup>b</sup> | 5mg/kg body weight /day up to 150 mg in two divided doses <sup>b</sup> | 100 mg twice daily <sup>c</sup>            | 100 mg twice daily <sup>c</sup>   | ≤100 mg/day             |
| <b>Rimantadine<sup>d</sup></b>            |                                                                        |                                                                        |                                            |                                   |                         |
| Treatment, <sup>e</sup> influenza A       | NA <sup>f</sup>                                                        | NA                                                                     | NA                                         | 100 mg twice daily <sup>c,g</sup> | 100 mg/day              |
| Prophylaxis, influenza A                  | 5m/kg body weight /day up to 150 mg in two divided doses <sup>b</sup>  | 5mg/kg body weight /day up to 150 mg in two divided doses <sup>b</sup> | 100 mg twice daily <sup>c</sup>            | 100 mg twice daily <sup>c</sup>   | 100 mg/day <sup>h</sup> |
| <b>Zanamivir<sup>i,j</sup></b>            |                                                                        |                                                                        |                                            |                                   |                         |
| Treatment, influenza A and B              | NA                                                                     | 10 mg twice daily                                                      | 10 mg twice daily                          | 10 mg twice daily                 | 10 mg twice daily       |
| <b>Oseltamivir</b>                        |                                                                        |                                                                        |                                            |                                   |                         |
| Treatment, <sup>k</sup> influenza A and B | dose varies by child's weight <sup>l</sup>                             | dose varies by child's weight <sup>l</sup>                             | dose varies by child's weight <sup>l</sup> | 75 mg twice daily                 | 75 mg twice daily       |
| Prophylaxis, influenza A and B            | NA                                                                     | NA                                                                     | NA                                         | 75 mg/day                         | 75 mg/day               |

NOTE: Amantadine manufacturers include Endo Pharmaceuticals (Symmetrel (R)-tablet and syrup) and Geneva Pharms Tech (Amantadine HCL-capsule); USL Pharma (Amantadine HCL-capsule and tablet); and Alpharma, Carolina Medical, Copley Pharmaceutical, HiTech Pharma, Mikart, Morton Grove, and Pharmaceutical Associates (Amantadine HCL-syrup), and Sandoz. Rimantadine is manufactured by Forest Laboratories (Flumadine (R)-tablet and syrup); Corepharma , Impax Labs (Rimantadine HCL-tablet), and Amide Pharmaceuticals (Rimantadine HCL-tablet). Zanamivir is manufactured by GlaxoSmithKline (Relenza (R)-inhaled powder). Oseltamivir is manufactured by Roche Pharmaceuticals (Tamiflu (R)-tablet). Information based on data published by the U.S. Food and Drug Administration at [www.fda.gov](http://www.fda.gov), accessed 3/30/2005.

<sup>a</sup> The drug package insert should be consulted for dosage recommendations for administering amantadine to persons with creatinine clearance  $\leq 50$  ml/min/1.73m<sup>2</sup> .

<sup>b</sup> 5 mg/kg body weight of amantadine or rimantadine syrup = 1 tsp/2.2 lbs.

<sup>c</sup> Children aged  $\geq 10$  years who weigh  $< 40$  kg should be administered amantadine or rimantadine at a dosage of 5 mg/kg body weight /day.

<sup>d</sup> A reduction in dosage to 100 mg/day of rimantadine is recommended for persons who have severe hepatic dysfunction or those with creatinine clearance  $\leq 10$  mL/min. Other persons with less severe hepatic or renal dysfunction taking 100 mg/day of rimantadine should be observed closely, and the dosage should be reduced or the drug discontinued, if necessary.

<sup>e</sup> Approved by FDA only for treatment among adults.

<sup>f</sup> Not applicable.

<sup>g</sup> Rimantadine is approved by FDA for treatment among adults. However, certain experts in the management of influenza consider it appropriate for treatment among children. (See American Academy of Pediatrics, 2003 Red Book.)

<sup>h</sup> Older nursing-home residents should be administered only 100 mg/day of rimantadine. A reduction in dosage to 100 mg/day should be considered for all persons aged  $\geq 65$  years if they experience possible side effects when taking 200 mg/day.

<sup>i</sup> Zanamivir administered via inhalation using a plastic device included in the medication package. Patients will benefit from instruction and demonstration of the correct use of the device.

<sup>j</sup> Zanamivir is not approved for prophylaxis.

<sup>k</sup> A reduction in the dose of oseltamivir is recommended for persons with creatinine clearance  $< 30$  ml/min.

<sup>l</sup> The dose recommendation for children who weigh  $\leq 15$  kg is 30 mg twice a day. For children who weigh  $> 15$  to 23 kg, the dose is 45 mg twice a day. For children who weigh  $> 23$  to 40 kg, the dose is 60 mg twice a day. And for children who weigh  $> 40$  kg, the dose is 75 mg twice a day.







# supplement 8 community disease control and prevention TABLE OF CONTENTS

|                                                                                                  |              |
|--------------------------------------------------------------------------------------------------|--------------|
| <b>S8-I. RATIONALE .....</b>                                                                     | <b>S8-3</b>  |
| <b>S8-II. OVERVIEW .....</b>                                                                     | <b>S8-4</b>  |
| <b>S8-III. RECOMMENDATIONS FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS.....</b>             | <b>S8-4</b>  |
| A. Community preparedness for implementation of pandemic influenza<br>containment measures ..... | S8-4         |
| 1. Planning for disease control and containment .....                                            | S8-4         |
| 2. Legal preparedness.....                                                                       | S8-5         |
| 3. Planning for influenza clinics and hotlines.....                                              | S8-5         |
| 4. Public understanding of disease containment measures .....                                    | S8-6         |
| 5. Enforcement of community containment measures.....                                            | S8-6         |
| B. Management of patients infected with novel strains of influenza and their contacts.....       | S8-7         |
| 1. Patient isolation.....                                                                        | S8-7         |
| 2. Management of close contacts.....                                                             | S8-7         |
| 3. Data collection .....                                                                         | S8-8         |
| C. Containment of small clusters of infection with novel strains of influenza .....              | S8-8         |
| 1. Targeted chemoprophylaxis of disease clusters .....                                           | S8-8         |
| 2. Influenza hotlines and clinics.....                                                           | S8-9         |
| <b>S8-IV. RECOMMENDATIONS FOR THE PANDEMIC PERIOD .....</b>                                      | <b>S8-9</b>  |
| A. Containment measures for individuals.....                                                     | S8-9         |
| 1. Patient isolation.....                                                                        | S8-9         |
| 2. Management of contacts.....                                                                   | S8-9         |
| B. Community-based containment measures.....                                                     | S8-10        |
| 1. Measures that affect groups of exposed or at-risk persons .....                               | S8-10        |
| a) Quarantine of groups of exposed persons.....                                                  | S8-10        |
| b) Measures that apply to use of specific sites or buildings.....                                | S8-11        |
| 2. Measures that affect communities.....                                                         | S8-11        |
| a) Community-wide infection control measures.....                                                | S8-11        |
| b) Snow days and self-shielding.....                                                             | S8-12        |
| c) Closure of office buildings, shopping malls, schools, and public transportation .....         | S8-12        |
| d) Widespread community quarantine (cordon sanitaire) .....                                      | S8-12        |
| 3. Scaling back community containment measures.....                                              | S8-13        |
| <b>Box 1. Containment Measures: Terms and Definitions.....</b>                                   | <b>S8-14</b> |
| <b>Box 2. Graded Implementation of Community Containment Measures.....</b>                       | <b>S8-15</b> |
| <b>Table 1. Threshold Determinants for the Use of Community Containment Measures.....</b>        | <b>S8-16</b> |

|                    |                                                                       |       |
|--------------------|-----------------------------------------------------------------------|-------|
| <b>Appendix 1.</b> | Interventions for Community Containment.....                          | S8-17 |
| <b>Appendix 2.</b> | Preparedness Checklist for Community Containment Measures.....        | S8-23 |
| <b>Appendix 3.</b> | Recent Experience with Quarantine: the 2003 SARS Outbreak .....       | S8-26 |
| <b>Appendix 4.</b> | Principles of Modern Quarantine .....                                 | S8-27 |
| <b>Appendix 5.</b> | Frequently Asked Questions about Quarantine .....                     | S8-29 |
| <b>Appendix 6.</b> | Recommendations for Quarantine.....                                   | S8-31 |
| <b>Appendix 7.</b> | Evaluation of Homes and Facilities for Isolation and Quarantine ..... | S8-33 |

## S8-I. RATIONALE

The initial response to the emergence of a novel influenza subtype that spreads between people should focus on containing the virus at its source, if feasible, and preventing a pandemic. Once spread beyond the initial focus occurs and with introduction of the virus into the United States, the foci of containment activities will be public health and individual measures that attempt to slow and limit viral transmission. For the purposes of this document, containment measures refer to measures that attempt to fully limit transmission as well as those that attempt to slow transmission. Containment strategies aimed at controlling and slowing the spread of the virus might include measures that affect individuals (e.g., isolation of patients and monitoring their contacts) as well as measures that affect groups or entire communities (e.g., cancellation of public gatherings; implementation of community-wide snow days). Guided by epidemiologic data, state and local authorities will implement the most appropriate of these measures in efforts to maximize impact on disease transmission and minimize impact on individual freedom of movement. HHS will provide assistance to states and localities as requested, including sharing experience of others and providing advice on decision-making as the situation evolves. Although states and localities have primary responsibility for public health matters within their borders, including isolation and quarantine, under the authority of Section 361 of the Public Health Service Act (42 USC 264), the HHS Secretary may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States or from one state or possession into another.

Containment measures applied to individuals (e.g., isolation and quarantine) may have limited impact in preventing the transmission of pandemic influenza, due to the short incubation period of the illness, the ability of persons with asymptomatic infection to transmit virus, and the possibility that early symptoms among persons infected with a novel influenza strain may be non-specific, delaying recognition and implementation of containment. Nevertheless, during the Pandemic Alert Period with a less efficiently transmitted virus, these measures may have great effectiveness, slowing disease spread and allowing time for targeted use of medical interventions. In addition, implementing these measures early in a pandemic when disease is first introduced into the U.S. and when the scope of the outbreak is focal and limited may slow geographical spread and increase time for vaccine production and implementation of other pandemic response activities. Later, when disease transmission is occurring in communities around the U.S., individual quarantine is much less likely to have an impact and likely would not be feasible to implement. Thus, community-based containment measures (e.g., closing schools or restricting public gatherings) and emphasizing what individuals can do to reduce their risk of infection (e.g., hand hygiene and cough etiquette) may be more effective disease control tools.

Although there are few data from past pandemics to guide containment efforts, the potential effectiveness of strictly implemented movement restrictions is supported by historical accounts that describe the use of such measures in American Samoa and in some Alaskan villages during the pandemic of 1918–1919. American Samoa banned inbound and outbound travel and mail service and (unlike Western Samoa) remained influenza-free. In Alaska, quarantine and isolation measures apparently delayed introduction of pandemic influenza into the Alaskan interior for several months, and some isolated villages were completely spared. Today, much more extensive international and domestic travel and the interdependence between communities make it unlikely that strict restrictions could be effectively imposed and that, except in unique settings, communities could prevent outbreaks from occurring. Preliminary mathematical modeling results suggest that travel restrictions would need to be about 99% effective to delay introduction into a country by one to two months. Based on these results, the goals of containment activities during a pandemic should be to slow the spread of disease early after introduction into the U.S. and to limit the number of persons who become infected in community outbreaks throughout the pandemic.

## S8-II. OVERVIEW

**Supplement 8** provides recommendations to state and local partners on the use of disease containment strategies to prevent or decrease transmission at different phases of an influenza Pandemic Alert Period and Pandemic Period. Recommendations for the Interpandemic and Pandemic Alert Periods focus on preparedness planning for implementation of containment measures. They also outline actions that may be taken during the earliest stage of a pandemic when the first potential cases or disease clusters are detected. In this setting, individual-level containment measures (e.g., patient isolation and identification, monitoring, quarantine of contacts) may be useful in slowing the spread of pandemic influenza and may be used without causing undue strain on limited public health and other healthcare resources.

Recommendations for the Pandemic Period focus on measures that may be beneficial and practical when there is a large number of cases and extensive viral transmission. In such a setting, individual-level measures may no longer be effective or feasible (e.g., if most contacts cannot be traced in time to prevent further exposures; if staffing constraints make contact tracing impractical). In this setting, state and local health departments might consider measures that decrease social contact within groups or whole communities (e.g., self-shielding, cancellation of public events, snow days, quarantine of groups of exposed persons, widespread community quarantine). Effective use of community containment measures during a pandemic will require periodic assessment of the properties of the pandemic virus and the distribution and clinical presentation of the cases. Guidance on containment recommendations will be updated, as needed.

## S8-III. RECOMMENDATIONS FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS

### A. Community preparedness for implementation of pandemic influenza containment measures

Both individual and community-based containment measures raise legal, logistic, and social challenges that should be addressed during the Interpandemic Period. This section provides information on planning for disease control and containment, legal preparedness, planning for potential use of influenza hotlines (preparing for influenza clinics is discussed in **Supplement 3**), and the role of communications in preparing the public to accept the possible need for restrictive measures to reduce the spread of pandemic influenza. Appendix 2 provides additional guidance on these topics, as well as on preparedness activities related to management of cases and contacts, non-hospital-based isolation of cases, and implementation of community containment measures. Information on hospital preparedness for patient isolation is provided in **Supplement 3**.

#### 1. Planning for disease control and containment

Experience during the 2003 SARS outbreak (Appendix 3) suggests that local officials will face logistic, economic, ethical, legal, social, and psychological challenges in implementing disease control and containment measures during a Pandemic Alert and Pandemic Period. Although individual quarantine as a control measure is likely only to be used during the Pandemic Alert and very early during the Pandemic Period—for example, among communities where initial cases are introduced into the U.S.—all state and local health departments and tribal authorities should anticipate and prepare for the challenges of effectively implementing this measure by working with community partners to review the steps involved in establishing and maintaining quarantine facilities and procedures.

Key activities include (see Appendix 2):

- Identifying and engaging traditional partners (e.g., public health and healthcare workers) and non-traditional community partners (e.g., transportation workers) and inviting them to participate in preparedness planning and in pandemic influenza containment exercises and drills
- Identifying potential isolation and quarantine facilities

- Establishing procedures for medical evaluation and isolation of quarantined persons who exhibit signs of influenza-like illness (ILI)
- Developing tools and mechanisms to prevent stigmatization and provide mental health services to persons in isolation or quarantine, as well as to family members of affected persons and other community members
- Establishing procedures for delivering medical care, food, and services to persons in isolation or quarantine. These efforts should take into account the special needs of children and persons with disabilities.
- Developing protocols for monitoring and enforcing quarantine measures
- Ensuring legal authorities and procedures exist for various levels of movement restrictions
- Establishing procedures for issues related to employment compensation and job security

## 2. Legal preparedness

States, localities, and tribes have primary responsibility for public health matters within their borders, including isolation and quarantine. Current quarantine laws, regulations, and enforcement procedures vary widely from state to state. Many of these laws date to the 19th century. In response to a request from CDC, the Center for Law and the Public's Health at Georgetown and Johns Hopkins universities has developed a draft Model State Emergency Health Powers Act ([www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf](http://www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf)) to assist state and local health agencies in reviewing emergency public health powers to ensure they are adequate to respond to modern disease and bioterrorism concerns.

Under the authority of Section 361 of the Public Health Service Act (42 USC 264), the HHS Secretary may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States or from one state or possession into another. Under authority delegated by the HHS Secretary, the CDC Director may isolate and quarantine persons who have been exposed to or are infected with certain specified communicable diseases and are arriving into the United States from a foreign country or traveling from one state or possession into another (42 CFR 71.32(a) & 42 CFR 70.6). The communicable diseases for which individuals may be subject to federal quarantine are specified in an Executive Order of the President, upon recommendation of the HHS Secretary in consultation with the Surgeon General. The most recent Executive Order is Executive Order 13295 of April 4, 2003, as amended by Executive Order 13375 of April 5, 2005. The April 5 amendment added influenza that is causing or has the potential to cause a pandemic to the list of federal quarantinable diseases (<http://www.cdc.gov/ncidod/dq/index.htm>). In addition, under section 311 of the PHS Act (42 USC 243), HHS may cooperate with and aid state and local authorities in the enforcement of their quarantine and other health regulations.

New International Health Regulations (IHR) were recently adopted by the World Health Assembly, which requires member states to report cases of human infection caused by a new subtype. When WHO has determined that a particular event constitutes a public health emergency, the IHR require WHO to make a "real-time" response to the emergency. Based on the details specific to the emergency, the Director General of WHO will recommend measures for implementation by the affected state as well as by other states. These time-limited recommendations are made available to states and, subsequently, made public. Depending on the evidence, recommended measures could be modified or ended.

## 3. Planning for influenza clinics and hotlines

An influenza pandemic is likely to put great stress on the healthcare delivery system, in particular emergency departments. To prevent overwhelming demand from compromising the function of emergency departments, healthcare providers, organizations, and public health authorities should consider optimal methods for delivering assessment and care to individuals with probable influenza. This may include designating certain offices or clinics or otherwise discrete areas for screening, triage, and care of individuals with influenza-like illness. While the large majority of outpatient care during a pandemic will be provided by patients' usual medical care practitioner, health authorities may decide to establish special facilities (*influenza clinics*) to provide rapid medical assessment of potentially infected persons, as part of efforts to control and contain small,

well defined disease clusters (see S8-III.C), or in geographical areas that are medically underserved. Ill persons will be encouraged to call special *influenza hotlines* that provide advice on whether to stay home or to seek medical care. Local public health systems supporting hotlines as triage and information systems must be aware of the healthcare resources available in the community. These "community triage" efforts may help prevent hospitals from being overwhelmed with patients who do not require hospital-level care. Moreover, community triage efforts may also reduce the number of uninfected persons who mingle with infected persons at clinics and hospitals. Preparedness planning for establishing influenza hotlines includes:

- Establishing telephone hotline numbers that people can call to report specific symptoms (e.g., fever) that will be specified by the state health department and CDC
- Identifying sites, staff members, and volunteers
- Developing protocols for hotline staff members that include training components and triage decision trees or algorithms
- Establishing communication systems with influenza clinics, if they are established

Organization of outpatient care in a community and potential establishment of influenza clinics is discussed in **Supplement 3**.

#### **4. Public understanding of disease containment measures**

Community preparedness for implementation of both individual and community control measures can be enhanced during the Interpandemic Period by improving public understanding of the dangers of pandemic influenza and the benefits of community-wide disease control practices, including social-distancing measures that can prevent illness and death (Appendix 4). Strategies for disease control will be facilitated by clear communication of the rationale for—and duration of—containment measures.

Local public health education campaigns that involve community partners can build public confidence in the ability to cope with an influenza pandemic. Partners may include schools, faith-based organizations, community-based organizations, and other "civil society" institutions that can help educate the public and provide support to families and persons who are incapacitated by illness.

Local public health campaigns should explain how individual action (e.g., strict compliance with respiratory hygiene, staying home when ill) and community efforts (e.g., implementation of snow days and self-shielding) can help reduce disease transmission. Education campaigns can describe the criteria, justification, role, methodology, and duration of quarantine and the social, medical, and psychological ways in which persons will be supported during the quarantine period. They can also explain that quarantine—which temporarily restricts personal movement—is a collective action implemented for the common good. In addition, they can allay public concerns about privacy issues related to the provision of medical information to healthcare workers and public health officials. These key messages should be translated and modified as required to address the cultural and linguistic needs of local neighborhoods.

Key messages prepared for use during the Interpandemic Period can be adapted for use during an actual pandemic (see Appendix 5 and Supplement 10.)

#### **5. Enforcement and support of community containment measures**

Experience from the 2003 SARS outbreak suggests that quarantine applied on a voluntary basis can be sufficient to reduce disease transmission (see Appendix 3). This idea is in accordance with data from modeling studies that suggest that quarantine and other community-based measures may be effective even if compliance is less than perfect.<sup>1</sup> Nevertheless, states, localities, and tribes should be prepared to enforce individual and community-based containment measures, if needed. The role of other Federal agencies in enforcing community containment measures will be detailed in the Federal Pandemic Influenza Plan.

<sup>1</sup> Meltzer MI, Damon I, LeDuc JW, Millar JD. Modeling potential responses to smallpox as a bioterrorist weapon. *EIF*.2001. Nov-Dec:7(6):959-69.

## B. Management of patients infected with novel strains of influenza and their contacts

In this document, the term “novel strains of influenza” is used to refer to avian or animal influenza strains that can infect humans (like influenza A [H5N1]) and new or reemergent human viruses that cause cases or clusters of human disease. Guidance on the detection and identification of persons who might be infected with novel strains of influenza is provided in **Supplement 1**. Guidance on the clinical management of persons with novel influenza infection is provided in **Supplement 5**.

The choice of measures to contain the spread of novel strains of influenza during the Pandemic Alert Period will vary depending on the assessment of risk, as reflected in the three Pandemic Alert Phases described by WHO (Box 2).

### 1. Patient isolation

Infection control precautions and procedures for isolating influenza patients—at home or in a residence, community facility, or hospital—are described in Supplement 4. The patient will be admitted to a hospital if clinically indicated, if public health needs require it, or if isolation at home or in a community facility cannot be achieved safely and effectively. Information for evaluating the suitability of homes and facilities for patient isolation is provided in Appendix 6.

The state or local health department, in consultation with federal agencies, will advise the healthcare provider and healthcare facility on additional steps that may be taken, before and after laboratory test results become available, via the state public health laboratory or CDC.

### 2. Management of close contacts

In most situations—even at the earliest stages of a pandemic—it will not likely be possible to trace and quarantine close contacts of suspected or confirmed cases within 48 hours (the average incubation period for human influenza). However, in certain situations, especially during the later phases of the WHO Pandemic Alert Period (Box 2), efforts to identify exposed individuals or groups might be recommended. Examples might include:

- Suspected or confirmed cases of novel influenza. For example, a suspected or confirmed case of avian influenza A (H5N1) in persons who have traveled to an H5N1-affected country and have been exposed to sick poultry (either through handling or eating poultry products) or a laboratory-confirmed human case of H5N1 influenza
- Suspected or confirmed cases of avian influenza A (H5N1) or another novel strain of influenza in travelers on airplanes or cruise ships about to arrive in the United States (see Supplement 9)
- Suspected or confirmed cases of avian influenza of any type in persons with known exposure to sick poultry or birds in the United States
- Clusters of avian influenza A (H5N1) or another novel strain of influenza in small, well defined settings, such as a military base
- Cases of laboratory exposure to avian influenza A (H5N1) or influenza viruses with the potential to cause a pandemic (e.g., influenza A [H2N2])

Decisions on whether to trace a patient's contacts and how to manage them will be made on a case-by-case basis by local and/or state public health departments, in consultation with CDC, taking into consideration:

- Likelihood that the suspected case is due to a novel influenza strain (based on symptoms and travel history, if laboratory results are not yet available)
- Likelihood that the causative virus is transmitted from person-to-person with a moderate or high efficiency (as reflected in the designated Pandemic Alert phase)



- Feasibility of conducting contact-tracing given the short incubation period for influenza

A patient's close contacts may include family, friends, work colleagues, classmates, fellow passengers, and/or healthcare providers. Management of contacts might include passive or active monitoring without activity restrictions and/or quarantine at home or in a designated facility. In the Pandemic Alert Period, especially during Phase 3 or 4 when little or limited person-to-person transmission has been documented, quarantine of contacts should be implemented **only when there is a high probability that the ill patient is infected with a novel influenza strain that may be transmitted to others.**

Contacts who are quarantined should be monitored by a health department official (or designee) at least once a day—by phone or in person—to assess symptoms and address any needs. Frequent monitoring (e.g., twice a day) will facilitate early detection, reducing the interval between the onset of symptoms and the isolation of the sick person. Early signs of influenza include fever, respiratory symptoms, and chills, rigors, myalgia, headache, or diarrhea. Quarantine may be lifted as soon as the exposed contact has remained without signs or symptoms of disease for a complete incubation period for influenza disease. (Experience with seasonal influenza suggests the incubation period is 1–4 days, with an average length of 2 days. However, the clinical behavior of a novel influenza virus may be different and could potentially be as long as 10 days. Pandemic influenza preparedness activities should plan for containment measures that may last between 1–10 days. For the purposes of this document, 10 days is referred to as the incubation period; however, public health authorities should be prepared to adjust the time frame as more is known about the virus.) Additional information on monitoring and evaluating persons in quarantine is provided in Appendix 6.

### 3. Data collection

Public health officials or designees should collect information on cases and contacts, including:

- Number of contacts identified per case
- Information on each contact:
  - Relationship to the case-patient
  - Nature and time of exposure
  - Whether the contact was vaccinated or on antiviral prophylaxis
  - Underlying medical conditions
- Number of contacts (including any in quarantine) that become ill
- Number of days between onset of symptoms and reporting to health officials

These data will guide decision-making on whether to implement more stringent containment measures.

## C. Containment of small clusters of infection with novel strains of influenza

Community-based control measures that state and local health officials might use to contain small clusters of infection with novel strains of influenza (during the later Pandemic Alert phases or when cases are first introduced into the U.S.) include targeted chemoprophylaxis and early detection of new cases by use of influenza hotlines and clinics. These approaches may be implemented in small, well defined settings. They are not likely to be useful once a pandemic is underway.

### 1. Targeted chemoprophylaxis of disease clusters

This intervention includes investigation of disease clusters, administration of antiviral treatment to persons with confirmed or suspected pandemic influenza, and provision of drug prophylaxis to all likely exposed persons in the affected community. CDC will assist state health departments in these efforts, as needed.

Targeted chemoprophylaxis also requires intensive disease surveillance to ensure coverage of the entire affected area, effective communication with the affected community, and rapid distribution and administration of antivirals because they are most effective when provided within 48 hours of symptom onset or when used as post-exposure prophylaxis before onset of illness

## 2. Influenza hotlines and clinics

During the later phases of a Pandemic Alert, in a community experiencing a disease cluster, a combination of self-assessment and establishment of influenza hotlines may be effective in detecting potential influenza disease and conducting "community triage" to direct persons with symptoms to the appropriate site and level of care. This intervention includes asking all members of the affected community to monitor their symptoms in accordance with instructions from the state health department and CDC. For example, all members of the community might be asked to take their temperature (and the temperature of their household members) once or twice daily. Persons with temperatures above a certain level may be asked to either stay home and phone a designated influenza hotline for a medical referral, or proceed to a neighborhood influenza clinic established by local public health and healthcare authorities.

Healthcare workers at the clinic will determine whether the patient's symptoms are likely due to pandemic influenza, to a different contagious disease, or to a noncontagious condition. If a person is judged likely to be infected with pandemic influenza, they will be referred for isolation and care as needed.

The establishment of hotlines and influenza clinics requires preparation to identify sites and personnel and to facilitate the procurement and distribution of thermometers and other supplies. Clinic personnel should be prepared to keep records and report cases, as requested, by state health departments and CDC.

## S8-IV. RECOMMENDATIONS FOR THE PANDEMIC PERIOD

During the Pandemic Period, control measures such as contact tracing and quarantine applied to individuals may have limited impact in decreasing influenza transmission. In addition, individual-level measures may no longer be feasible. During this stage, state and local health departments should consider measures that decrease social contact within groups or whole communities (e.g., self-shielding, cancellation of public events, snow days) and measures that individuals can take personally to decrease their risk of infection

Box 2 outlines measures that may be employed at different stages of a pandemic, as disease becomes more widespread. These begin with containment activities for individuals and move on, as needed, to community-based measures. Depending on the specific circumstances of an epidemic, these steps may not necessarily be taken in sequential order.

## A. Containment measures for individuals

### 1. Patient isolation

As noted above, a patient with a suspected or confirmed case of pandemic influenza should be separated from persons who are well, using infection control measures described in **Supplement 4**. If a surge in patients overwhelms healthcare capacity or if home isolation is not feasible, health departments may need to use alternative facilities for isolation of influenza patients. Guidance on use of alternative facilities for isolation of influenza patients is provided in **Appendix 7**.

### 2. Management of contacts

Contact tracing, contact monitoring, and quarantine of close contacts may be effective only in special situations during the earliest stages of a pandemic. Because the usefulness and feasibility of these measures will be limited once the pandemic has started to spread, health authorities should consider community-based measures that reduce disease transmission by increasing social distance.

## B. Community-based containment measures

If disease transmission in the community is significant and sustained, state and local public health authorities should consider implementing community-based containment measures. CDC will promote an active process of engagement and discussion to help states and localities decide what actions to take as the situation evolves. Community-based containment measures can be grouped into two broad categories: measures that affect groups of exposed or at-risk persons and measures that affect entire communities.

Table 1 lists quantifiable factors that may influence decisions on where and when to impose community-based containment measures. Social considerations—including levels of community cooperation and mobility—will also inform local decision-making.

### 1. Measures that affect groups of exposed or at-risk persons

Measures that affect groups of exposed or at-risk persons include:

- Quarantine of groups of exposed persons
- Containment measures that apply to use of specific sites or buildings

These measures should be considered when:

- There is limited disease transmission in the area.
- Most cases can be traced to contact with an earlier case or exposure to a known transmission setting (e.g., a school or workplace where a person has fallen ill).
- The intervention is likely to either significantly slow the spread of infection or to decrease the overall magnitude of an outbreak in the community.

#### a) Quarantine of groups of exposed persons

The purpose of quarantine is to reduce influenza transmission by separating exposed persons from others, monitoring exposed persons for symptoms, and providing medical care and infection control precautions as soon as symptoms are detected. Groups that might be quarantined include:

- Persons who might have been exposed to an influenza case
  - Via family members
  - At a public gathering
  - On an airplane or cruise ship or other closed conveyance (see also Supplement 9)
  - At their school or workplace
- Healthcare providers who work at a facility where influenza cases receive care

Group quarantine (like patient isolation) is optimally performed on a voluntary basis, in accordance with instructions of healthcare providers and health officials. However, many levels of government (local, state, federal) have the basic legal authority to compel mandatory isolation and quarantine of individuals and groups when necessary to protect the public's health (see below). Recommendations for quarantine and monitoring of quarantined persons in different situations (home quarantine, quarantine in a designated facility, working quarantine) are provided in Appendix 6.

### b) Measures that apply to use of specific sites or buildings

Two ways of increasing social distance activity restrictions are to cancel events and close buildings or to restrict access to certain sites or buildings. These measures are sometimes called "focused measures to increase social distance." Depending on the situation, examples of cancellations and building closures might include:

- Cancellation of public events (concerts, sports events, movies, plays)
- Closure of recreational facilities (community swimming pools, youth clubs, gymnasiums)

## 2. Measures that affect communities

Measures that affect entire communities (including both exposed and non-exposed persons), include:

- Promotion of community-wide infection control measures (e.g., respiratory hygiene/cough etiquette)
- Snow days and self-shielding
- Closure of office buildings, shopping malls, schools, and public transportation (e.g., subways, buses; see Supplement 9)
- Widespread community quarantine (*cordon sanitaire*)

Measures that affect whole communities should be considered when:

- There is moderate to extensive disease transmission in the area.
- Many cases cannot be traced to contact with an earlier case or known exposure.
- Cases are increasing among contacts of influenza patients.
- There is a significant delay between the onset of symptoms and the isolation of cases because of the large number of ill persons.

As community outbreaks of pandemic influenza occur, community-wide infection control measures may decrease the overall magnitude of the outbreak (see Box 3). Community-based measures may also include school closures, snow days, and self-shielding.

### a) Community-wide infection control measures

Throughout a pandemic, public health authorities will encourage all persons with signs and symptoms of a respiratory infection, regardless of presumed cause, to:

- Cover the nose/mouth when coughing or sneezing.
- Use tissues to contain respiratory secretions.
- Dispose of tissues in the nearest waste receptacle after use.
- Perform hand hygiene after contact with respiratory secretions and contaminated objects or materials.

Persons at high risk for complications of influenza will be advised to avoid public gatherings (e.g., movies, religious services, public meetings) when pandemic influenza is in the community. They should also avoid going to other public areas (e.g., food stores, pharmacies); the use of other persons for shopping or home delivery service is encouraged.

Disposable surgical-type masks are used by healthcare workers taking care of ill patients to prevent splashes and droplets of potentially infectious material (e.g., from coughs and sneezes) from reaching the mucous membranes of the healthcare worker's nose or mouth. The benefit of wearing masks by well persons in public settings has not been established and is not recommended as a public health control measure at this time. In contrast to healthcare workers who necessarily have close contact with ill patients, the general public should try to avoid close contact with ill individuals.

Nevertheless, persons may choose to wear a mask as part of individual protection strategies that include cough etiquette, hand hygiene, and avoiding public gatherings. Mask use may be most important for persons who are at high risk for complications of influenza and those who are unable to avoid close contact with others or must travel for essential reasons such as seeking medical care. Public education should be provided on how to use and dispose of masks appropriately. In addition, this education should emphasize that mask use is not a substitute for social distance or other personal protection measures (see also Supplement 4). Supply issues should be considered so that mask use in communities does not limit availability for healthcare settings where the importance and effectiveness of this use has been documented.

#### **b) Snow days and self-shielding**

Implementation of "snow days"—asking everyone to stay home—involves the entire community in a positive way, is acceptable to most people, and is relatively easy to implement. Snow days may be instituted for an initial 10-day period, with final decisions on duration based on an epidemiologic and social assessment of the situation. States and local authorities may wish to consider recommendations to the public for acquisition and storage of necessary provisions including type and quantity of supplies needed during snow days. Snow days can effectively reduce transmission without explicit activity restrictions (i.e., quarantine). Consideration should be given to personnel who maintain primary functions in the community (e.g., law enforcement personnel, transportation workers, utility workers [electricity, water, gas, telephone, sanitation]). Compliance with snow days might be enhanced by "self-shielding" behavior (i.e., many people may stay home even in the absence of an official snow day ["reverse quarantine"]).

#### **c) Closure of office buildings, shopping malls, schools, and public transportation**

Closure of office buildings, stores, schools, and public transportation systems may be feasible community containment measures during a pandemic. All of these have significant impact on the community and workforce, however, and careful consideration should be focused on their potential effectiveness, how they can most effectively be implemented, and how to maintain critical supplies and infrastructure while limiting community interaction. For example, when public transportation is cancelled, other modes of transportation must be provided for emergency medical services and medical evaluation.

Although data are limited, school closures may be effective in decreasing spread of influenza and reducing the overall magnitude of disease in a community. In addition, the risk of infection and illness among children is likely to be decreased, which would be particularly important if the pandemic strain causes significant morbidity and mortality among children. Children are known to be efficient transmitters of seasonal influenza and other respiratory illnesses. Anecdotal reports suggest that community influenza outbreaks may be limited by closing schools. Results of mathematical modeling also suggest a reduction of overall disease, especially when schools are closed early in the outbreak. During a Pandemic Period, parents should be encouraged to consider child care arrangements that do not result in large gatherings of children outside the school setting.

#### **d) Widespread community quarantine (*cordon sanitaire*)**

In extreme circumstances, public health officials may consider the use of widespread or community-wide quarantine, which is the most stringent and restrictive containment measure. Strictly speaking, "widespread community quarantine" is a misnomer, since "quarantine" refers to separation of exposed persons only and (unlike snow days) usually allows provision of services and support to affected persons. Like snow days, widespread community quarantine involves asking everyone to stay home. It differs from snow days in two respects: 1) It may involve a legally enforceable action, and 2) it restricts travel into or out of an area circumscribed by a real or virtual "sanitary barrier" or "*cordon sanitaire*" except to authorized persons, such as public health or healthcare workers.

Implementation of this measure during a pandemic is unlikely to prevent the introduction or spread of pandemic disease except in uncommon or unique circumstances (such as in a community able to be completely self-sufficient). In many cases, other less restrictive approaches such as snow days can be implemented to slow disease spread or decrease its magnitude in

a community. Because of this, *cordon sanitaire* is not recommended during a pandemic unless a community is in a setting where it is likely to be applied effectively and has planned with neighboring jurisdictions how such an approach would be implemented and maintained during a pandemic.

### 3. Scaling back community containment measures

The decision to discontinue community-level measures must balance the need to lift individual movement restrictions against community health and safety. Premature removal of containment strategies can increase the risk of additional transmission. Decisions should be based on evidence of improving local/regional control, such as:

- Consistent decrease in the number of confirmed cases
- Reduction in the number of probable and known cases
- Effective protective countermeasures are in place (e.g., high coverage with a pandemic influenza vaccine)

General recommendations are to withdraw the most stringent or disruptive measures first (e.g., widespread community quarantine, snow days, mass transit interruptions).

## BOX 1. CONTAINMENT MEASURES: TERMS AND DEFINITIONS

**Isolation** is the separation and restriction of movement or activities of ill infected persons (patients) who have a contagious disease, for the purpose of preventing transmission to others.

**Quarantine** is the separation and restriction of movement or activities of persons who are not ill but who are believed to have been exposed to infection, for the purpose of preventing transmission of disease. Individuals may be quarantined at home or in designated facilities; healthcare providers and other response workers may be subject to quarantine when they are off duty.

**Quarantine of close contacts** refers to the quarantine of individuals exposed to patients with communicable diseases (e.g., family members, work or school mates, healthcare workers).

**Quarantine of groups of exposed persons** refers to quarantine of people who have been exposed to the same source of illness (e.g., a case of influenza at a public gathering, on an airline, train, or cruise ship, at a school or workplace or apartment complex, or at a recently visited store or office).

**Widespread or community-wide quarantine** refers to the closing of community borders or the erection of a real or virtual barrier around a geographic area (a cordon sanitaire) with prohibition of travel into or out of the area.

**Self-shielding** refers to self-imposed exclusion from infected persons or those perceived to be infected (e.g., by staying home from work or school during an epidemic).

**Snow days** are days on which offices, schools, transportation systems are closed or cancelled, as if there were a major snowstorm.

**Influenza clinics** are special facilities that may be established during a pandemic to provide rapid medical assessment of potentially infected persons. Ill persons would be encouraged to call influenza hotlines that provide advice on whether to stay home or seek help at an influenza clinic. Persons who come to an influenza clinic will be advised on whether they may be best served by hospital care or home care.

**Individual-level containment measures** include isolation of patients and management of their close contacts.

**Focused measures to increase social distance (or decrease social contact)** includes measures applied to groups rather than individuals or whole communities (e.g., quarantine of groups of exposed persons and measures that apply to the use of specific sites or buildings).

**Containment measures that apply to use of specific sites or buildings** include cancellation of public events (e.g., concerts, sports events, movies and plays), closure of office buildings, apartment complexes, or schools; and closure of subways or bus lines. These measures may also involve restricting entrance to buildings or other sites (e.g., requiring fever screening or use of face masks before entry to schools, worksites, or airplanes).

**Community-based measures to increase social distance** include measures applied to whole neighborhoods, towns, or cities (e.g., snow days, establishment of fever clinics, and community-wide quarantine).



**BOX 2. GRADED IMPLEMENTATION OF COMMUNITY CONTAINMENT MEASURES**

| Level of influenza activity                                                                                                                                                                                           | Response                                                                                                                      |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|
| No novel influenza strains of public health concern in global circulation                                                                                                                                             | Preparedness planning                                                                                                         |
| Limited novel influenza virus <sup>2</sup> transmission abroad; all local cases are either imported or have clear epidemiologic links to other cases                                                                  | Quarantine of close contacts                                                                                                  |
| Limited novel influenza virus transmission in the area, with either a small number of cases without clear epidemiologic links to other cases or with increased occurrence of influenza among their close contacts     | Quarantine of close contacts                                                                                                  |
| Sustained novel influenza virus transmission in the area, with a large number of cases without clear epidemiologic links to other cases; control measures aimed at individuals and groups appear to be effective      | Focused measures to increase social distance; <sup>3</sup> consider community-based measures                                  |
| Sustained novel influenza activity in the area, with a large number of cases in persons without an identifiable epidemiologic link at the time of initial evaluation; control measures are believed to be ineffective | Community-level measures to increase social distance; consider snow days and community-wide quarantine                        |
| Decreases in the number of new cases, unlinked (or "unexpected") cases, and generations of transmission                                                                                                               | Quarantine of contacts                                                                                                        |
| Transmission has been controlled or eliminated; no new cases reported                                                                                                                                                 | Active monitoring in high-risk populations; continue for 2-3 incubation periods after control or elimination of transmission. |

<sup>2</sup> "Novel influenza viruses" include avian or animal influenza strains that can infect humans (like avian influenza A [H5N1]) and new or reemergent human viruses that cause cases or clusters of human disease.

<sup>3</sup> "Focused measures to increase social distance" include measures applied to groups rather than individuals or whole communities (e.g., quarantine of groups of exposed persons and measures that apply to the use of specific sites or buildings)

**TABLE 1. THRESHOLD DETERMINANTS FOR THE USE OF COMMUNITY CONTAINMENT MEASURES**

Data on cases and contacts—as well as on depletion of healthcare and public health resources over the course of a pandemic—can help state and local health authorities decide when to implement community-level containment measures. As part of preparedness planning, state and local health agencies and healthcare partners may estimate at what point in the pandemic—in terms of such variables as numbers of cases and numbers of unoccupied hospital beds—that more extensive measures may be imposed. During an actual pandemic, state and local departments may also evaluate social considerations, such as levels of community cooperation and mobility.

| Potential parameters                                   | Variable                                                                                                                                                                                                                                                                                                                                                                                                                              |
|--------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Cases and contacts</b>                              | Number of cases (absolute or estimated)<br>Rate of incident cases<br>Number of hospitalized cases<br>Number and percentage of cases with no identified epidemiologic link<br>Morbidity (including disease severity) and mortality<br>Number of contacts under surveillance and/or quarantine                                                                                                                                          |
| <b>Healthcare resources</b>                            | Hospital/facility bed capacity<br>Staff resources<br>Patient/staff ratio<br>Number of ill or absent staff members<br>Availability of specifically trained specialists and ancillary staff members<br>Availability of ventilators<br>Availability of other respiratory equipment<br>Availability of personal protective equipment and other measures<br>Availability of therapeutic medications (influenza and non-influenza specific) |
| <b>Public health resources</b>                         | Investigator to case and contact ratios<br>Number of contacts under active surveillance<br>Number of contacts under quarantine<br>Ability to rapidly trace contacts (number of untraced/interviewed contacts)<br>Ability to implement and monitor quarantine (staff member to contact ratio)<br>Ability to provide essential services (food, water, etc.)                                                                             |
| <b>Community cooperation, mobility, and compliance</b> | Degree of compliance with voluntary individual isolation<br>Degree of compliance with active surveillance and voluntary individual quarantine<br>Degree of movement out of the community<br>Degree of compliance with community-containment measures                                                                                                                                                                                  |

## APPENDIX 1. INTERVENTIONS FOR COMMUNITY CONTAINMENT

Contacts of pandemic influenza patients can be managed by use of a range of interventions, all of which are designed to facilitate early recognition of illness in persons at greatest risk of becoming infected and thereby prevent transmission to others. Whereas many of these interventions are applied individually to persons identified as contacts of a person with possible or known influenza disease, others are applied to larger groups of persons, or communities, that share a similar risk of exposure. Measures applied to individuals may not be feasible during the Pandemic Period, when quarantining individuals and tracing close contacts may not be possible. The range of interventions includes the following:

### Passive Monitoring

|                           |                                                                                                                                                                                                                                                                                |
|---------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Definition</i>         | The contact is asked to perform self-assessment at least twice daily and to contact authorities immediately if respiratory symptoms and/or fever occur.                                                                                                                        |
| <i>Application</i>        | Situations in which 1) the risk of exposure and subsequent development of disease is low, and 2) the risk to others if recognition of disease is delayed is also low                                                                                                           |
| <i>Benefits</i>           | Requires minimal resources<br>Places few constraints on individual movement                                                                                                                                                                                                    |
| <i>Challenges</i>         | Relies on self-reporting<br>Affected persons may not perform an adequate self-assessment                                                                                                                                                                                       |
| <i>Resources Required</i> | Supplies (thermometer; symptom log; written instructions)<br>Hotline to notify authorities about symptoms or needs<br>Staff to receive telephone reports and provide in-person evaluation and care<br>Plans and procedures for rapid isolation of persons who develop symptoms |
| <i>Partners</i>           | Household members                                                                                                                                                                                                                                                              |
| <i>Forms/Templates</i>    | Symptom logs<br>Instructions for patients and healthcare workers                                                                                                                                                                                                               |

### Active Monitoring without Explicit Activity Restrictions

|                           |                                                                                                                                                                                                                                                             |
|---------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Definition</i>         | A healthcare or public health worker evaluates the contact on a regular (at least daily) basis by phone and/or in person for signs and symptoms suggestive of influenza                                                                                     |
| <i>Application</i>        | Situations in which 1) the risk of exposure to and subsequent development of disease is moderate to high, 2) resources permit close observation of individuals, and 3) the risk of delayed recognition of symptoms is low to moderate                       |
| <i>Benefits</i>           | Places few constraints on individual liberties                                                                                                                                                                                                              |
| <i>Challenges</i>         | Requires adequate staffing<br>Requires a system to track information and to verify monitoring and appropriate actions based on findings                                                                                                                     |
| <i>Resources Required</i> | Trained staff to provide in-person and/or telephone evaluations<br>Plans and procedures for rapid isolation of persons who develop symptoms<br>Contingency plans for managing noncompliant persons<br>Hotline to notify authorities about symptoms or needs |

|                        |                                                                                                                                                                                          |
|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Partners</i>        | Professional and lay healthcare workers to perform evaluations on behalf of the health department<br>Possible need for law enforcement to assist with management of noncompliant persons |
| <i>Forms/Templates</i> | Checklist for assessment of active monitoring<br>Template for recording results of clinical evaluation                                                                                   |

## Active Monitoring with Activity Restrictions (Quarantine)

|                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|---------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Definition</i>         | <p>The contact remains separated from others for a specified period (up to 10 days after potential exposure), during which s/he is assessed on a regular basis (in person at least once daily) for signs and symptoms of influenza disease. Persons with fever, respiratory, or other early influenza symptoms require immediate evaluation by a trained healthcare provider. Restrictions may be voluntary or legally mandated; confinement may be at home or in an appropriate facility.</p> <p>No specific precautions are required for those sharing the household with a person in quarantine as long as the person remains asymptomatic. Because onset of symptoms may be insidious, it may be prudent to minimize interactions with household members during the period of quarantine, if feasible</p> |
| <i>Application</i>        | Situations in which the risk of exposure and subsequent development of disease is high and the risk of delayed recognition of symptoms is moderate                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <i>Benefits</i>           | Reduces risk of spread from persons with subacute or subclinical presentations or from delayed recognition of symptoms                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <i>Challenges</i>         | <p>May infringe on personal movement</p> <p>May lead to a feeling of isolation from family and friends</p> <p>May lead to loss of income or employment</p> <p>Requires plans/protocols for provision of essential services</p> <p>Requires plan for provision of mental health support</p> <p>Risk of noncompliance, particularly as duration increases</p> <p>May require enforcement for noncompliance</p>                                                                                                                                                                                                                                                                                                                                                                                                  |
| <i>Resources Required</i> | <p>Staff for monitoring and evaluation</p> <p>Appropriate facility if home setting is unavailable or inadequate</p> <p>Staff, funding, and goods for provision of essential services</p> <p>Hotline for notification of symptoms or personal needs</p> <p>Mechanisms to communicate with family members outside the household or facility</p> <p>Mental health and social support services</p> <p>Delivery systems for food and other essential supplies</p>                                                                                                                                                                                                                                                                                                                                                  |
| <i>Partners</i>           | <p>Professional and lay healthcare workers to perform assessments on behalf of the health department</p> <p>Community volunteers/workers to assist with provision of essential services</p> <p>Potential need for law enforcement to assist with noncompliant persons</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

|                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Forms/Templates</i> | <ul style="list-style-type: none"> <li>Checklist for active monitoring</li> <li>Template for recording results of clinical evaluation</li> <li>Checklist and guidelines for evaluation of homes for quarantine</li> <li>Checklist and guidelines for evaluation of community-based sites for quarantine</li> <li>Guidelines for monitoring compliance with home quarantine</li> <li>Guidelines for monitoring compliance with quarantine in community-based facilities</li> <li>Forms for recording compliance with quarantine</li> </ul> |
| <i>Examples</i>        | <ul style="list-style-type: none"> <li>Home quarantine (voluntary or mandatory)</li> <li>Facility quarantine (voluntary or mandatory)</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                          |

## Working Quarantine

|                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|---------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Definition</i>         | <p>Employees are permitted to work but must observe activity restrictions while off duty. Monitoring for influenza-like illness before reporting for work is usually required. This may change based on the clinical presentation of the pandemic strain. Use of appropriate PPE while at work is required (see <b>Supplement 4</b>)</p>                                                                                                                                                                                                                                              |
| <i>Application</i>        | <p>Persons for whom activity restrictions (home or facility quarantine) are indicated but who provide essential services (e.g., healthcare workers)</p>                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <i>Benefits</i>           | <ul style="list-style-type: none"> <li>Reduces risk of community spread from high-risk contacts while minimizing adverse impact of activity restrictions on provision of essential services</li> <li>Clinical monitoring at work reduces the staff required for active monitoring at the quarantine site</li> </ul>                                                                                                                                                                                                                                                                   |
| <i>Challenges</i>         | <ul style="list-style-type: none"> <li>Need for close and consistent pre-shift monitoring at the work site to prevent inadvertent exposures</li> <li>May require means of transporting persons to and from work site to minimize interactions; persons in working quarantine should wear appropriate PPE during transport. (See <b>Supplement 4</b>)</li> <li>Must maintain close cooperation and communication between work site and local health authorities</li> <li>Need to provide mental health services to address concerns about isolation from family and friends</li> </ul> |
| <i>Resources Required</i> | <ul style="list-style-type: none"> <li>Appropriate facility for off-duty quarantine if home is unavailable or inadequate</li> <li>Staff, funding, and goods for provision of essential services</li> <li>Personal protective equipment (see <b>Supplement 4</b>)</li> <li>Hotline for notification of symptoms and personal needs</li> <li>System to track results of work-site monitoring and location(s) of off-duty quarantine</li> <li>Mental health, psychological, and behavioral support services, especially if work includes care of influenza patients</li> </ul>           |
| <i>Partners</i>           | <ul style="list-style-type: none"> <li>Work-site administrators and infection control personnel</li> <li>Community volunteers/workers</li> <li>Staff/volunteers to assist with transportation to and from work</li> <li>Mental health professionals</li> <li>Potential need for law enforcement to assist with noncompliant persons</li> </ul>                                                                                                                                                                                                                                        |

|                        |                                                               |
|------------------------|---------------------------------------------------------------|
| <i>Forms/Templates</i> | Guidelines and instructions for persons in working quarantine |
|                        | Instructions for supervisors of persons in working quarantine |
|                        | Checklist to evaluate homes for quarantine                    |
|                        | Guidelines for monitoring compliance                          |
|                        | Checklist for active monitoring at work site                  |
|                        | Template for recording results of clinical evaluation         |
|                        | Forms for recording compliance                                |

## Focused Measures to Increase Social Distance

|                           |                                                                                                                                                                                                                                                                                                                                                                  |
|---------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Definition</i>         | Intervention applied to specific groups, designed to reduce interactions and thereby transmission risk within the group. When focused, the intervention is applied to groups or persons identified in specific sites or buildings, most but not necessarily all of whom are at risk of exposure to influenza.                                                    |
| <i>Examples</i>           | Quarantine of groups of exposed persons<br>Cancellation of public events<br>Closure of office buildings, schools, and/or shopping malls; closure of public transportation such as subways or bus lines                                                                                                                                                           |
| <i>Application</i>        | Groups or settings where transmission is believed to have occurred, where the linkages between cases is unclear at the time of evaluation, and where restrictions placed only on persons known to have been exposed is considered insufficient to prevent further transmission                                                                                   |
| <i>Benefits</i>           | Applied broadly, reduces the requirement for urgent evaluation of large numbers of potential contacts to determine indications for activity restrictions<br>May enable reductions in transmission among groups of persons without explicit activity restrictions (quarantine)                                                                                    |
| <i>Challenges</i>         | May be difficult to solicit cooperation, particularly if popular buildings are closed or popular events are cancelled<br>Requires excellent communication mechanisms to notify affected persons of details and rationale<br>May need to provide replacement for affected activities (e.g., school, essential services)<br>Generally relies on passive monitoring |
| <i>Resources Required</i> | Systems to communicate relevant messages<br>May require enforcement, particularly if closure of buildings or gathering places is necessary<br>Requires resources for passive monitoring<br>Hotlines to report symptoms and obtain follow-up instructions<br>Transportation for medical evaluation, with appropriate infection control precautions                |
| <i>Partners</i>           | News media and communication outlets<br>Law enforcement<br>Community groups                                                                                                                                                                                                                                                                                      |
| <i>Forms/Templates</i>    | Messages for affected persons<br>Messages for employers of affected persons<br>Messages for persons supplying essential services                                                                                                                                                                                                                                 |

## Community-Wide Measures to Increase Social Distance

|                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|---------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Definition</i>         | Intervention applied to an entire community or region, designed to reduce personal interactions and thereby transmission risk. The prototypical example is implementation of a "snow day," in which offices, schools, and transportation systems are cancelled as for a major snowstorm.                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <i>Examples</i>           | Snow days                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <i>Application</i>        | All members of a community in which 1) extensive transmission of influenza is occurring, 2) a significant number of cases lack clearly identifiable epidemiologic links at the time of evaluation, and 3) restrictions on persons known to have been exposed are considered insufficient to prevent further spread                                                                                                                                                                                                                                                                                                                                                                                                               |
| <i>Benefits</i>           | <p>Reduces need for urgent evaluation of large numbers of potential contacts to determine indications for activity restrictions</p> <p>May enable reductions in transmission among groups without explicit activity restrictions (quarantine)</p> <p>"Snow days" are familiar concepts and thus are easy to implement on short notice</p>                                                                                                                                                                                                                                                                                                                                                                                        |
| <i>Challenges</i>         | <p>May be difficult to solicit cooperation</p> <p>Requires excellent communication mechanisms to notify affected persons of details and rationale</p> <p>May need to provide replacement for affected activities (e.g., school, essential services)</p> <p>May need to address mental health and financial support issues</p> <p>When an entire community is involved, requires cooperation with neighboring jurisdictions that may not be using a similar intervention, particularly in situations where persons live in one city and work in another and only one locale is affected by the intervention</p> <p>Generally relies on passive monitoring</p> <p>Social and economic impact of public transportation closures</p> |
| <i>Resources Required</i> | <p>Communication outlets</p> <p>Enforcement</p> <p>Resources for passive monitoring</p> <p>Hotlines and other communication systems to report symptoms and obtain follow-up instructions</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <i>Partners</i>           | <p>News media and other communication outlets</p> <p>Law enforcement and transportation officials to enforce restrictions (e.g., closure of bridges, roads, or mass transit systems) and plan for provision of critical supplies and infrastructure</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <i>Forms/Templates</i>    | <p>Messages for affected persons</p> <p>Messages for employers of affected persons</p> <p>Messages for persons supplying essential services</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

## Widespread Community Quarantine, Including Cordon Sanitaire

|                   |                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Definition</i> | Legally enforceable action that restricts movement into or out of the area of quarantine of a large group of people or community; designed to reduce the likelihood of transmission of influenza among persons in and to persons outside the affected area. When applied to all inhabitants of an area (typically a community or neighborhood), the intervention is referred to as <i>cordon sanitaire</i> (sanitary barrier). |
|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|



|                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|---------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Application</i>        | All members of a group in which 1) extensive transmission is occurring, 2) a significant number of cases lack identifiable epidemiologic links at the time of evaluation, and 3) restrictions placed on persons known to have been exposed are considered insufficient to prevent further spread. Widespread quarantine is unlikely to be necessary because other less restrictive measures (e.g., snow days) may be equally effective.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <i>Benefits</i>           | Reduces need for urgent evaluation of large numbers of potential contacts to determine indications for activity restrictions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <i>Challenges</i>         | <p>Controversial because of the degree that individual movement is restricted</p> <p>Difficult to solicit cooperation for extended periods, particularly if the rationale is not readily apparent or was not clearly explained</p> <p>Requires excellent communication mechanisms to inform affected persons and to maintain public confidence in the appropriateness of the chosen course of action</p> <p>Need to ensure continuation of essential services</p> <p>Need to provide financial support and mental health support services for the affected population</p> <p>When an entire community is involved, requires cooperation with neighboring jurisdictions that may not be using a similar intervention, particularly in situations where persons live in one city and work in another and only one locality is affected by the intervention</p> <p>Need to provide mechanisms for isolating symptomatic persons with minimal delay</p> |
| <i>Resources Required</i> | <p>Systems to communicate relevant messages</p> <p>Enforcement to maintain security at borders</p> <p>Transportation for persons requiring medical evaluation, with appropriate infection control precautions</p> <p>Staff and supplies to maintain access to and availability of essential services and goods, including food, water, medicine, medical care, and utilities</p> <p>Psychological support staff</p> <p>Plan to divert flow of critical infrastructure supplies and materials that normally transit through quarantined area</p>                                                                                                                                                                                                                                                                                                                                                                                                     |
| <i>Partners</i>           | <p>News media and other mass communication outlets</p> <p>Public and private groups, industries, and officials to coordinate supply and provision of essential services to affected area</p> <p>Law enforcement to maintain security at borders and to enforce movement restrictions</p> <p>Transportation industry</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <i>Forms/Templates</i>    | <p>Messages for affected persons</p> <p>Messages for employers of affected persons</p> <p>Messages for persons supplying essential services</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <i>Examples</i>           | <p>Quarantine (<i>cordon sanitaire</i>) of a city or town</p> <p>Quarantine of occupants of a housing complex or office building</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |

## APPENDIX 2. PREPAREDNESS CHECKLIST FOR COMMUNITY CONTAINMENT MEASURES

### General

- ☐ Establish an incident command structure that can be used for influenza response.
- ☐ Establish a legal preparedness plan.
- ☐ Establish relationships with partners, such as law enforcement, first responders, healthcare facilities, mental health professionals, local businesses, and the legal community.
- ☐ Plan to monitor and assess factors that will determine the types and levels of response, including the epidemiologic profile of the outbreak, available local resources, and level of public acceptance and participation.
- ☐ Develop communication strategies for the public, government decision-makers, healthcare and emergency response workers, mental health professionals, and the law enforcement community.
- ☐ Invite key partners to participate in pandemic influenza containment exercises and drills.

### Management of cases and contacts (including quarantine)

- ☐ Develop protocols, tools, and databases for:
  - Case surveillance
  - Clinical evaluation and management
  - Contact tracing, monitoring, and management
  - Reporting criteria
- ☐ Develop standards and tools for home and non-hospital isolation and quarantine.
- ☐ Establish supplies for non-hospital management of cases and contacts.
- ☐ Establish a telecommunications plan for "hotlines" or other services for:
  - Case and contact monitoring and response
  - Fever triage
  - Public information
  - Provider information
- ☐ Plan to ensure provision of essential services and supplies to persons in isolation and quarantine, keeping in mind the special needs of children. Services and supplies include:
  - Food and water
  - Shelter
  - Medicines and medical consultations
  - Mental health and psychological support services
  - Other supportive services (e.g., day care or elder care)
  - Transportation to medical treatment, if required
- ☐ Plan to address issues of financial support, job security, and prevention of stigmatization.
- ☐ Establish procedures for medical evaluation and isolation of quarantined persons who exhibit signs of illness.

- ☐ Develop protocols for monitoring and enforcing quarantine measures, such as:
  - Protocols for follow-up of persons who cannot be reached by telephone. These may include a threshold period for nonresponsiveness that should trigger a home visit or other means to locate the person. Partnerships with law enforcement and other community-based resources will be helpful in tracing the whereabouts of persons who have violated restrictions.
  - Protocols for monitoring persons who cannot or will not comply with voluntary home quarantine. These may include:
    - Issuing official, legally binding quarantine orders
    - Posting a guard outside the home
    - Using electronic forms of monitoring
    - Using guarded facilities
  - Protocols for using checkpoints to restrict travel between neighborhoods.

### **Temporary emergency facilities for patient isolation quarantine, and assessment of patients with fever (see Appendix 7 for a list of facility characteristics)**

- ☐ Identify appropriate community-based facilities for isolation of patients who have no substantial healthcare requirements.
- ☐ Develop policies related to use of these facilities.
- ☐ Identify facilities for persons for whom home isolation is indicated but who do not have access to an appropriate home setting, such as travelers and homeless populations.
- ☐ Ensure that required procedures for assessment of potential isolation or quarantine sites are available and up to date.
- ☐ Identify potential quarantine facilities and prepare contingency plans for staffing and equipping them.
- ☐ Identify potential sites for fever clinics and prepare contingency plans for staffing and equipping them, including the ability to dispense antiviral drugs to identified cases in the priority groups.

### **Community containment measures**

- ☐ Ensure that legal authorities and procedures are in place to implement the various levels of movement restrictions as necessary.
- ☐ Establish procedures for medical evaluation and isolation of quarantined persons who exhibit signs of illness. (Additional information on medical evaluation is provided in Supplement 5.)
- ☐ Develop tools and mechanisms to prevent stigmatization and provide mental health services to persons in isolation or quarantine.
- ☐ Identify key partners and personnel for the implementation of movement restrictions, including quarantine, and the provision of essential services and supplies:
  - Law enforcement
  - First responders
  - Other government service workers
  - Utilities
  - Transportation industry
  - Local businesses
  - Schools and school boards

Establish procedures for delivering medical care, food, and services to persons in isolation or quarantine. Examples of services that will require the help of non-traditional partners include:

- ☐ Training for responders and healthcare workers, as necessary, in use of personal protective equipment
- ☐ Plans for the mobilization and deployment of public health and other community-service personnel

## General

- ☐ Establish an incident command structure that can be used for influenza response.
- ☐ Establish a legal preparedness plan.
- ☐ Establish relationships with partners, such as law enforcement, first responders, healthcare facilities, mental health professionals, and the legal community.
- ☐ Plan to monitor and assess factors that will determine the types and levels of response, including the epidemiologic profile of the outbreak, available local resources, and level of public acceptance and participation.
- ☐ Develop communication strategies for the public government decision-makers, healthcare and emergency response workers, mental health professionals, and the law enforcement community. These strategies should consider privacy concerns.
- ☐ Invite key partners to participate in pandemic influenza containment exercises and drills.

## Management of cases and contacts (including quarantine)

- ☐ Develop protocols, tools, and databases for management of cases and contacts, considering account security and privacy concerns. These may include protocols for:
  - Case surveillance
  - Clinical evaluation and management
  - Contact tracing, monitoring, and management
  - Reporting criteria
- ☐ Develop standards and tools for home and non-hospital isolation and quarantine.
- ☐ Establish supplies for non-hospital management of cases and contacts.
- ☐ Establish a telecommunications plan for "hotlines" or other services for case and contact monitoring and response
  - Fever triage
  - Public information
  - Provider information
- ☐ Plan to ensure provision of essential services and supplies to persons in isolation and quarantine, including:
  - Food and water
  - Shelter
  - Medicines and medical consultations
  - Mental health and psychological support services
  - Other supportive services (e.g., day care or elder care).
  - Transportation to medical treatment, if required
- ☐ Plan to address issues of financial support, job security, privacy concerns and prevention of stigmatization.

### APPENDIX 3. RECENT EXPERIENCE WITH QUARANTINE: THE 2003 SARS OUTBREAK

Large-scale quarantine strategies were implemented during the 2003 SARS outbreak in several severely affected countries. Strategies included quarantine of close contacts in healthcare and household settings, work and school contacts, travelers arriving from other SARS-affected areas, and in some cases, of entire apartment complexes or areas of a city. Other strategies used to control and prevent SARS transmission in these countries included 1) requiring fever screening before entry to schools, work sites, and other public buildings; 2) requiring use of face masks in certain settings, such as public transportation systems; 3) implementing population-wide temperature monitoring and SARS fever hotlines and referral services; and 4) implementing community-level disinfection strategies.

The impact and effectiveness of individual isolation and quarantine measures and community- and population-level interventions undertaken to contain the SARS epidemic globally are not yet fully understood, but some important generalizations can be made. Overall, strategies associated with timely and successful control of local outbreaks were characterized by rapid and aggressive use of case and contact identification and community containment strategies.

Other lessons learned from this modern experience with community containment include the following:

- Strict infection control measures were needed for isolation of SARS patients; these may be difficult to implement in home and community settings.
- Community control measures such as cancellation of public events and other "snow day" measures may have reduced the risk of exposure to SARS at the population level by limiting social interactions.
- Although quarantine of individual contacts was an integral part of SARS control in most settings, quarantine of large groups was used only in selected settings where transmission was extensive.
- To be effective, quarantine did not have to be mandatory and compliance did not have to be 100%; voluntary compliance with quarantine requests was >90% in most settings.
- A variety of quarantine strategies (e.g., home quarantine, working quarantine) were used, depending on specific needs.
- Isolation and quarantine raised legal, social, financial, psychological, and logistical challenges (e.g., financial support, provision of services, prevention of stigmatization and discrimination) that should be anticipated and addressed in the future. Meeting the social, financial, and psychological needs of persons in isolation and quarantine and their contacts was key to the successful application of containment measures.
- Effective implementation of quarantine required a clear understanding of the roles and legal authorities of local, state, and federal public health officials.
- Effective implementation of quarantine required identification and engagement of appropriate traditional and non-traditional partners (e.g., law enforcement) in coordinated planning and response.
- The financial, social, and psychological impact of quarantine measures is substantial; preparedness planning should include measures to reduce this impact.
- Obtaining and maintaining public trust are key to successful implementation of these measures; clear messages about the criteria, justification, role, and duration of quarantine and ways in which persons will be supported during the quarantine period will help generate public trust.

## APPENDIX 4. PRINCIPLES OF MODERN QUARANTINE

The goal of quarantine is to protect the public by separating those exposed to a dangerous communicable disease from the general population. It represents collective action for the common good that is predicated on aiding individuals who are already infected or exposed and protecting others from inadvertent exposure. Principles of modern quarantine<sup>4</sup> include:

Principle 1. Modern quarantine is used when:

- A person or a well defined group of people has been exposed to a highly dangerous and highly contagious disease
- Resources are available to care for quarantined people
- Resources are available to implement and maintain the quarantine and deliver essential interventions

Principle 2. Modern quarantine encompasses a range of disease-containment strategies, including:

- Short-term, voluntary home-curfew
- Restrictions on the assembly of groups of people (e.g., school events)
- Cancellation of public events
- Suspension of public gatherings and closings of public places (e.g., theaters)
- Restrictions on travel (air, rail, water, motor vehicle, pedestrian)
- Closure of mass transit systems
- Snow days
- "Cordon sanitaire" (a guarded barrier restricting passage in and out of an area)

Principle 3. Modern quarantine is used in combination with other interventions and public health tools, including:

- Enhanced disease surveillance and symptom monitoring
- Rapid diagnosis and treatment for those who fall ill
- Preventive interventions for quarantined individuals, including vaccination or prophylactic treatment, depending on the disease

Principle 4. Quarantined individuals will be sheltered, fed, and cared for under the supervision of trained healthcare professionals. They will also be among the first to receive all available medical interventions to prevent and control disease, including:

- Vaccination (e.g., in the case of smallpox)
- Antibiotics (e.g., in the case of plague)
- Early and rapid diagnostic testing and symptom monitoring
- Early treatment if symptoms appear

Quarantined people may be cared for at home, in a designated emergency facility, or in a specialized hospital, depending on the disease and the available resources.

<sup>4</sup> These principles apply to the use of quarantine as a control measure against a wide variety of infectious diseases.

Principle 5. Modern quarantine lasts only as long as necessary to protect the public by providing public health interventions (e.g., immunization or drug treatment, as required) and ensuring that quarantined persons do not become ill or infect others.

Principle 6. Modern quarantine does not have to be absolute to be effective. Modeling exercises suggest that partial quarantine can be effective in slowing the rate of smallpox spread, especially when combined with vaccination. The goal is to reduce the reproductive rate (the number of secondary cases from an index case) to  $< 1$  to extinguish an epidemic.

Principle 7. Modern quarantine is more likely to involve limited numbers of exposed persons in small area, than to involve large numbers of persons in whole neighborhoods or cities. The small areas may be thought of as "boxes" or "concentric circles" drawn around individual disease cases. Logistical issues will vary in each case, depending on the size and location of the boxes.

Examples of "boxes" include:

- People on an airplane or cruise ship on which a passenger is ill with a suspected quarantinable disease
- People who have contact with a contagion-infected person whose source of disease exposure is unknown

Principle 8. Implementation of modern quarantine requires a clear understanding of public health roles at the local, state, and federal levels, based on well understood legal authorities at each level.

Principle 9. Implementation of modern quarantine requires coordinated preparedness planning by many public and private response partners, including agencies and groups involved in public health, healthcare, transportation, emergency response, law enforcement, and security.

Principle 10. Implementation of modern quarantine requires the trust and participation of the general public, who must be informed about the dangers of quarantinable diseases before an outbreak occurs, as well as during an actual event.



## APPENDIX 5. FREQUENTLY ASKED QUESTIONS ABOUT QUARANTINE

### If an influenza pandemic occurs, will my community be quarantined?

Community-wide quarantine is only one of a spectrum of actions that may be considered during an influenza pandemic in the United States. Although rapid control is likely to require bold and swift action, measures that are less drastic than legally enforced quarantine may suffice, depending on the epidemiologic characteristics of the pandemic. For example, active monitoring without activity restrictions may be adequate when most cases are either imported or have clear epidemiologic linkages at the time of initial evaluation. When the epidemiology of the outbreak indicates a need for stronger measures, jurisdictions can adopt a voluntary quarantine approach and reserve compulsory measures for only extreme situations. When an outbreak progresses to include large numbers of cases for which no epidemiologic linkages can be identified, community-level interventions may become necessary. Even at this stage, however, measures designed to increase social distance, such as snow days, may be preferred alternatives to quarantine. Wider use of quarantine is generally reserved for situations in which all other control measures are believed to be ineffective.

The choice of containment measures requires frequent and ongoing assessment of an outbreak and evaluation of the effectiveness of existing control measures. Officials must be prepared to make decisions based on limited information and then modify those decisions as additional information becomes available.

### Does the effectiveness of containment measures require 100% compliance?

No. Containment measures, including quarantine, are effective even if compliance is less than 100%. Although health officials should strive for high compliance, even partial or “leaky” quarantine can reduce transmission. Therefore, strict enforcement is not always needed; in most cases, jurisdictions can rely on voluntary cooperation. The incremental benefit of quarantine approaches a maximum at a compliance rate of approximately 90%, with little additional benefit from higher rates of compliance. Therefore, containment measures can be important components of the response to a communicable disease outbreak even when compliance is not 100%.

### Does “quarantine” always mean using a legal order to restrict someone’s activity?

No. The term “quarantine” is often defined narrowly to refer to the legally mandated separation of well persons who have been exposed to a communicable disease from those who have not been exposed. Although the precise legal definition of quarantine may differ from jurisdiction to jurisdiction, when used clinically or programmatically, quarantine may be defined more broadly to include all interventions, both mandatory and voluntary, that restrict the activities of persons exposed to a communicable disease. Therefore, whenever an exposed person is placed under a regimen of monitoring that includes an activity restriction, even when those restrictions are voluntary, the person is said to be under quarantine.

### Must quarantine be mandatory to be effective?

Although the federal government and nearly all states have the basic legal authority to place persons exposed to certain communicable diseases under quarantine and enforce the required restrictions on activity, use of this authority may not always be necessary or practical. Previous experiences with the use of quarantine, including those during the 2003 SARS outbreak, suggest that the majority of persons comply voluntarily with requests from health authorities to remain in quarantine and observe the recommended activity restrictions. In the event voluntary measures are not successful, it may be necessary to implement mandatory containment measures.

### **Does being placed in quarantine increase a person's risk for acquiring disease?**

One of the fundamental principles of modern quarantine is that persons in quarantine are to be closely monitored so that those who become ill are efficiently separated from those who are well. A second principle is that persons in quarantine should be among the very first to receive any available disease-prevention interventions. Adherence to these two principles of modern quarantine should prevent an increase in risk for acquiring disease while in quarantine.

### **Is quarantine really necessary if everyone who develops symptoms is rapidly placed in isolation?**

Although theoretically true, it would be unrealistic to believe that even the most efficient system for initiation of isolation will minimize delays to the extent required to prevent transmission. Among the factors contributing to delays in recognition of symptoms are the insidious nature of disease onset and denial that symptoms have developed. Early in the 2003 SARS outbreak in Singapore, the average delay from onset of symptoms to initiation of isolation was 7 days. Officials were able to reduce this delay only to 3 days, even with an aggressive public awareness campaign on the importance of symptom recognition and isolation.

Quarantine helps to reduce transmission associated with delays in isolation in two ways. First, quarantine enables health officials to quickly locate symptomatic persons who should be placed in isolation. Second, although quarantine locations may not be as efficient as isolation facilities in preventing transmission, quarantine reduces the number of persons who might be exposed while awaiting transfer to an isolation facility. If quarantine was not used, symptomatic and infectious persons could move about freely in public places, potentially exposing large numbers of additional persons and thereby fueling the outbreak.

### **Is quarantine useful only for diseases that are spread by the airborne route?**

No. Quarantine simply refers to the separation and restriction of activity of persons exposed to a communicable disease who are not ill. It is designed to minimize interactions between those exposed to a disease and those not yet exposed. As such, quarantine can be used for any disease that is spread from person to person. In practice, however, because of the activity restrictions associated with quarantine, the intervention is generally reserved for diseases like SARS or pandemic influenza that are easily and rapidly spread from person to person. The indication for quarantine for diseases purely transmitted by the airborne route is clear. However, this tool can also be useful where transmission can occur through close personal contact with secretions or objects contaminated by an ill person. Smallpox is an excellent example of a disease where quarantine can be effective in controlling spread although transmission may occur by means other than the airborne route.

### **Will the public accept the use of quarantine?**

Yes. The negative connotations associated with quarantine likely stem from its misuse or abuse in the past. Although inappropriate use of quarantine, either voluntary or mandatory, would not and should not be accepted by the public, efforts should be made to gain public acceptance when use of this measure is indicated. Experiences with the use of quarantine during the SARS outbreaks of 2003 suggest that public acceptance of quarantine may be greater than previously thought. For example, during the 2003 SARS outbreak in Canada, almost all persons asked to observe quarantine restrictions did so willingly, with only a small number requiring a legal order to gain cooperation. In all cases, cooperation and acceptance was achieved through clear and comprehensive communication with the public about the rationale for use of quarantine.

## APPENDIX 6. RECOMMENDATIONS FOR QUARANTINE

(Note: Recommendations on patient isolation are provided in Supplement 3.)

### General considerations

- Monitor each quarantined person daily, or more frequently if feasible, for fever, respiratory symptoms, and other symptoms of early influenza disease.
- Monitor compliance with quarantine through daily visits or telephone calls.
- Provide a hotline number for quarantined persons to call if they develop symptoms or have other immediate needs.
- If a quarantined person develops symptoms suggestive of influenza, arrangements should be in place for separating that person from others in quarantine and ensuring immediate medical evaluation.
- Provide persons in quarantine with all needed support services, including 1) psychological support, 2) food and water, 3) household and medical supplies, and 4) care for family members who are not in quarantine. Financial issues, such as medical leave, may also need to be considered.
- Collect data related to quarantine activities to guide ongoing decision-making including information on each person quarantined:
  - Relationship to the case-patient
  - Nature and time of exposure
  - Whether the contact was vaccinated or on antiviral prophylaxis or using PPE
  - Underlying medical conditions
  - Number of days in quarantine
  - Symptom log
  - Basic demographics
  - Compliance with quarantine

Based on current available data, the recommended duration of quarantine for influenza is generally **10 days** from the time of exposure. (This period may be adjusted based on available information during a pandemic.) At the end of the designated quarantine period, contacts should have a final assessment for fever and respiratory symptoms. Persons without fever or respiratory symptoms may return to normal activities.

### Home quarantine

Whenever possible, contacts should be quarantined at home. Home quarantine requires the fewest additional resources, although arrangements must still be made for monitoring patients, reporting symptoms, transporting patients for medical evaluation if necessary, and providing essential supplies and services. Home quarantine is most suitable for contacts with a home environment that can meet their basic needs and in which unexposed household members can be protected from exposure. Other considerations include:

- Persons in home quarantine must be able to monitor their own symptoms (or have them monitored by a caregiver).
- The person's home should be evaluated for suitability before being used for quarantine, using a questionnaire administered to the quarantined person or the caregiver. Additional guidance on use of a residence for quarantine is provided in Appendix 7.

- Quarantined persons should minimize interactions with other household members to prevent exposure during the interval between the development and recognition of symptoms. Precautions may include 1) sleeping and eating in a separate room, 2) using a separate bathroom, and 3) appropriate use of personal protective equipment (see **Supplement 4**).
- Persons in quarantine may be assessed for symptoms by either active or passive monitoring. Active monitoring of contacts in quarantine may overcome delays resulting from the insidious onset of symptoms or denial among those in quarantine.
- Household members may go to school, work, etc., without restrictions unless the quarantined person develops symptoms. If the quarantined person develops symptoms, household members should remain at home in a room separate from the symptomatic person and await additional instructions from health authorities.
- Household members can provide valuable support to quarantined persons by helping them feel less isolated and ensuring that essential needs are met.
- Immediate and ongoing psychological support services should be provided to minimize psychological distress.
- Quarantined persons should be able to maintain regular communication with their loved ones and healthcare providers.

### **Quarantine in designated facilities**

In some cases, affected persons may not have access to an appropriate home environment for quarantine. Examples include travelers; persons living in dormitories, homeless shelters, or other group facilities; and persons whose homes do not meet the minimum requirements for quarantine. In other instances, contacts may have an appropriate home environment but may not wish to put family members at risk. In these situations, health officials should identify an appropriate community-based quarantine facility. Monitoring of quarantined persons may be either passive or active, although active monitoring may be more appropriate in a facility setting. Facilities designated for quarantine of persons who cannot or choose not to be quarantined at home should meet the same criteria listed for home quarantine. Evaluation of potential sites for facility-based quarantine is an important part of preparedness planning (see Appendix 7).

### **Working quarantine**

This type of quarantine applies to healthcare workers or other essential personnel who are at occupational risk of influenza infection. These groups may be subject to quarantine either at home or in a designated facility during off-duty hours. When off duty, contacts on working quarantine should be managed in the same way as persons in quarantine at home or in a designated facility. Local officials should:

- Monitor persons in working quarantine for symptoms during work shifts
- Promptly evaluate anyone who develops symptoms
- Provide transportation to and from work, if needed
- Develop mechanisms for immediate and ongoing psychological support

At the end of the designated quarantine period, contacts should receive physical (fever and respiratory symptoms) and psychological health assessments. Persons without fever or respiratory symptoms may return to normal activities. Persons who exhibit psychological distress should be referred to mental health professionals for additional support services.

## APPENDIX 7. EVALUATION OF HOMES AND FACILITIES FOR ISOLATION AND QUARANTINE

### ISOLATION FACILITIES

#### Home isolation

Ideally, persons who meet the criteria for a case of pandemic influenza and who do not require hospitalization for medical reasons should be isolated in their homes. The home environment is less disruptive to the patient's routine than isolation in a hospital or other community setting.

If feasible—especially during the earliest stages of a pandemic—a home being considered as an isolation setting should be evaluated by an appropriate authority, which could be the patient's physician, health department official, or other appropriate person to verify its suitability. The assessment should center on the following minimum standards for home isolation of an influenza patient:

#### Infrastructure

- Functioning telephone
- Electricity
- Heating, ventilation, and air conditioning (HVAC)
- Potable water
- Bathroom with commode and sink
- Waste and sewage disposal (septic tank, community sewage line)

#### Accommodations

- Ability to provide a separate bedroom for the influenza patient
- Accessible bathroom in the residence; if multiple bathrooms are available, one bathroom designated for use by the influenza patient

#### Resources for patient care and support

- Primary caregiver who will remain in the residence and who is not at high risk for complications from influenza disease
- Meal preparation
- Laundry
- Banking
- Essential shopping
- Social diversion (e.g., television, radio, Internet access, reading materials)
- Masks, tissues, hand hygiene products, and information on infection control procedures
- Educational material on proper waste disposal

## Isolation in a community-based facility

When persons requiring isolation cannot be accommodated either at home or in a healthcare facility, a community-based isolation facility will be required. The availability of a community-based facility will be particularly important during a large outbreak (See also <http://www.ahrq.gov/research/altsites.htm>).

Much of the work in identifying and evaluating potential sites for isolation should be conducted in advance of an outbreak as part of preparedness planning. Each jurisdiction should assemble a team (including infection control specialists, public health authorities, engineers, sanitation experts, and mental health specialists) to identify appropriate locations and resources for community influenza isolation facilities, establish procedures for activating them, and coordinate activities related to patient management. The team should consider the use of both existing and temporary structures. Options for existing structures include community health centers, nursing homes, apartments, schools, dormitories, and hotels. Options for temporary structures include trailers, barracks, and tents. Considerations include:

### Basic infrastructure requirements

- Meets all local code requirements for a public facility
- Functioning telephone system
- Electricity
- Heating, ventilating, and air conditioning (HVAC)
- Potable water
- Bathroom with commode and sink
- Waste and sewage disposal (septic tank, community sewage line)
- Multiple rooms for housing ill patients (individual rooms are preferred)

### Access considerations

- Proximity to hospital
- Parking space
- Ease of access for delivery of food and medical and other supplies
- Handicap accessibility
- Basic security

### Space requirements

- Administrative offices
- Offices/areas for clinical staff
- Holding area for contaminated waste and laundry
- Laundry facilities (on- or off-site)
- Meal preparation (on- or off-site)

### Social support resources

- Television and radio
- Reading materials

To determine priorities among available facilities, consider these features:

- Separate rooms for patients or areas amenable to isolation of patients with minimal construction
- Feasibility of controlling access to the facility and to each room
- Availability of potable water, bathroom, and shower facilities
- Facilities for patient evaluation, treatment, and monitoring
- Capacity for providing basic needs to patients
- Rooms and corridors that are amenable to disinfection
- Facilities for accommodating staff
- Facilities for collecting, disinfecting, and disposing of infectious waste
- Facilities for collecting and laundering infectious linens and clothing
- Ease of access for delivery of patients and supplies
- Legal/property considerations

Additional considerations include:

- Staffing and administrative support
- Training
- Ventilation and other engineering controls
- Ability to support appropriate infection control measures
- Availability of food services and supplies
- Ability to provide an environment that supports the social and psychological well-being of patients
- Security and access control
- Ability to support appropriate medical care, including emergency procedures
- Access to communication systems that allow for dependable communication within and outside the facility
- Ability to adequately monitor the health status of facility staff

## QUARANTINE FACILITIES

### Home quarantine

A person's residence is generally the preferred setting for quarantine. As with isolation, home quarantine is often least disruptive to a person's routine. Because persons who have been exposed to influenza may need to stay in quarantine for as long as 10 days (may be modified based on information about the virus), it is important to ensure that the home environment meets the individual's ongoing physical, mental, and medical needs. An evaluation of the home for its suitability for quarantine should be performed, ideally before the person is placed in quarantine. This evaluation may be performed on site by a health official or designee. However, from a practical standpoint, it may be more convenient to evaluate the residence through the administration of a questionnaire to the individual and/or the caregiver. Factors to be considered in the evaluation include:

- Basic utilities (water, electricity, garbage collection, and heating or air-conditioning as appropriate)
- Basic supplies (clothing, food, hand-hygiene supplies, laundry services)
- Mechanism for addressing special needs (e.g., filling prescriptions)



- Mechanism for communication, including telephone (for monitoring by health staff, reporting of symptoms, gaining access to support services, and communicating with family)
- Accessibility to healthcare workers or ambulance personnel
- Access to food and food preparation
- Access to supplies such as thermometers, fever logs, phone numbers for reporting symptoms or accessing services, and emergency numbers (these can be supplied by health authorities if necessary)
- Access to mental health and other psychological support services.

### **Quarantine in a community-based facility**

Although the home is generally the preferred setting for quarantine, alternative sites for quarantine may be necessary in certain situations. For example, persons who do not have a home situation suitable for this purpose or those who require quarantine away from home (e.g., during travel) will need to be housed in an alternative location. Because persons who have been exposed to influenza may require quarantine for as long as 10 days, it is important to ensure that the environment is conducive to meeting the individual's ongoing physical, mental, and medical needs. Ideally, one or more community-based facilities that could be used for quarantine should be identified and evaluated as part of influenza preparedness planning. The evaluation should be performed on site by a public health official or designee. Additional considerations, beyond those listed above for home quarantine, include:

- Adequate rooms and bathrooms for each contact
- Delivery systems for food and other needs
- Staff to monitor contacts at least daily for fever and respiratory symptoms
- Transportation for medical evaluation for persons who develop symptoms
- Mechanisms for communication, including telephone (for monitoring by health staff, reporting symptoms, gaining access to support services, and communicating with family)
- Adequate security for those in the facility

**Services for removal of waste.** No special precautions for removal of waste are required as long as persons remain asymptomatic.



# **supplement 9** **managing travel-related risk of disease transmission** **TABLE OF CONTENTS**

|                                                                                                     |       |
|-----------------------------------------------------------------------------------------------------|-------|
| SUMMARY OF ROLES AND RESPONSIBILITIES IN MANAGING TRAVEL-RELATED RISK OF DISEASE TRANSMISSION ..... | S9-2  |
| S9-I. RATIONALE .....                                                                               | S9-3  |
| S9-II. OVERVIEW .....                                                                               | S9-3  |
| S9-III. RECOMMENDATIONS FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS.....                       | S9-3  |
| A. Preparedness for implementation of travel-related containment measures .....                     | S9-3  |
| 1. Engaging community partners .....                                                                | S9-4  |
| 2. Protocols for managing ill passengers at ports of entry .....                                    | S9-4  |
| 3. Quarantine preparedness at ports of entry .....                                                  | S9-5  |
| 4. Legal preparedness.....                                                                          | S9-5  |
| B. Health information for travelers.....                                                            | S9-6  |
| C. Evaluation of travel-related cases of infection with novel strains of influenza .....            | S9-6  |
| 1. Managing ill passengers .....                                                                    | S9-6  |
| 2. Managing travel contacts.....                                                                    | S9-7  |
| D. Preventing the importation of infected birds and animals.....                                    | S9-7  |
| S9-IV. RECOMMENDATIONS FOR THE PANDEMIC PERIOD .....                                                | S9-8  |
| A. Travel-related containment measures.....                                                         | S9-8  |
| 1. Travel into the United States.....                                                               | S9-8  |
| a) Managing arriving ill passengers.....                                                            | S9-8  |
| b) Travel health precautions and warnings.....                                                      | S9-9  |
| c) Travel-related measures at early stages of a pandemic .....                                      | S9-9  |
| d) Travel-related measures at later stages of a pandemic.....                                       | S9-9  |
| 2. Travel out of the United States.....                                                             | S9-10 |
| 3. Travel within the United States .....                                                            | S9-10 |
| B. De-escalation of travel-related control measures.....                                            | S9-11 |
| 1. Outbound passengers .....                                                                        | S9-11 |
| 2. Inbound passengers .....                                                                         | S9-11 |
| Box 1. CDC Quarantine Stations.....                                                                 | S9-12 |
| Box 2. Travel-Related Definitions .....                                                             | S9-13 |
| Appendix 1. Recent Experience with Travel-Related Containment Measures: the 2003 SARS Outbreak..... | S9-14 |
| Appendix 2. Travel-Related Influenza Response Matrices.....                                         | S9-16 |

## **SUMMARY OF PUBLIC HEALTH ROLES AND RESPONSIBILITIES IN MANAGING TRAVEL-RELATED RISK OF DISEASE TRANSMISSION**

### **INTERPANDEMIC AND PANDEMIC ALERT PERIODS**

#### **State and local responsibilities:**

- Improve readiness to implement travel-related disease containment measures.
- Work with CDC quarantine stations and federal partners to provide public health information to travelers who visit countries where avian or animal influenza strains that can infect humans (e.g., avian influenza A [H5N1]) or human strains with pandemic potential have been reported.
- Work with CDC quarantine stations and federal partners to evaluate and manage arriving ill passengers who might be infected with avian or animal influenza strains (e.g., avian influenza A [H5N1]) or human strains with pandemic potential.

#### **HHS responsibilities:**

- Work with state and local health departments to prevent the importation of influenza-infected birds and animals into the United States.
- Provide state and local health departments with legal preparedness templates for use in implementing quarantine and patient isolation measures.
- Work with travel industry partners to ensure that airplane and cruise ship captains and crew are familiar with procedures for identifying and managing arriving ill passengers.
- Coordinate with other countries and WHO to prevent the spread of novel influenza via international travel.

### **PANDEMIC PERIOD**

#### **State and local responsibilities:**

- Minimize travel-related disease transmission using a range of containment strategies.
- Evaluate the need to implement or terminate travel-related containment measures as the pandemic evolves.

#### **HHS responsibilities:**

- Work with state and local health departments and CDC quarantine stations to prevent the importation and exportation of cases of pandemic influenza.
- Promote a process of active engagement and discussion with state and local partners to support local decision-making on implementation of travel restrictions and other travel-related containment strategies.
- Coordinate with other countries and WHO to prevent the spread of pandemic influenza via international travel.

## S9-I. RATIONALE

The 2003 pandemic of severe acute respiratory syndrome (SARS) demonstrated how quickly human respiratory viruses can spread, especially in a world of modern air travel (Appendix 1). Disease spread will likely be even faster during an influenza pandemic because a typical influenza virus has a shorter average incubation period (typically 2 days vs. 7–10 days for SARS-associated coronavirus [SARS-CoV]) and is more efficiently transmitted from person to person.

If an influenza pandemic begins outside the United States, public health authorities might screen inbound travelers from affected areas to decrease disease importation into the United States. If a pandemic begins in or spreads to the United States, health authorities might screen outbound passengers to decrease exportation of disease. Early in a pandemic, state and local health departments might also implement domestic travel-related measures to slow disease spread within the United States.

Because some persons infected with influenza will still be in the incubation period, be shedding virus asymptomatically, or have mild symptoms, it will not be possible to identify and isolate all arriving infected or ill passengers and quarantine their fellow passengers. Moreover, if an ill passenger is identified after leaving the airport, it might not be possible to identify all travel contacts within the incubation period for influenza. Nevertheless—depending on the situation—these activities might slow spread early in a pandemic, allowing additional time for implementation of other response measures such as vaccination.

Once a pandemic is underway, exit screening of travelers from affected areas ("source control") is likely to be more efficient than entry screening to identify ill travelers. Early in a pandemic, this intervention may decrease disease introductions into the U.S. Later, however, as pandemic disease spreads in communities, ongoing indigenous transmission will likely exceed new introductions and, therefore, federal authorities might modify or discontinue this strategy. Voluntary limitations on travel during a pandemic alert and pandemic, as persons decide to limit their own personal risk by canceling nonessential trips, will also decrease the amount of disease spread. Limiting or canceling travel of U.S. residents and others from affected countries will depend on the properties of the pandemic virus that emerges, and will be informed by the facts on the ground at the time of emergence.

## S9-II. OVERVIEW

Supplement 9 provides recommendations to state and local partners on travel-related containment strategies that can be used during different phases of an influenza pandemic. These strategies range from distribution of travel health alert notices, to isolation and quarantine of new arrivals, to restriction or cancellation of nonessential travel. State and local health departments will implement these strategies in coordination with CDC quarantine stations located at 18 U.S. ports of entry (Box 1). The recommendations for the Interpandemic and Pandemic Alert Periods focus on preparedness planning and on management of arriving ill passengers on international flights or cruise ships. The recommendations for the Pandemic Period focus on travel-related measures to decrease disease spread into, out of, and within the United States.

## S9-III. RECOMMENDATIONS FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS

### A. Preparedness for implementation of travel-related containment measures

If a pandemic begins outside the United States, early application of travel-related control measures (i.e., identification and isolation of ill travelers, quarantine of close contacts) might slow the introduction of the virus into the United States, allowing more time for healthcare preparedness efforts. The effectiveness of these measures might be limited because asymptomatic travelers can transmit disease, travelers in the incubation phase might not become symptomatic until after arrival at their

destinations, and it might not be possible to trace contacts within the incubation period for influenza. Results of mathematical models suggest that even with international flights, if persons are asymptomatic but incubating influenza when they board, they may remain asymptomatic when they arrive and therefore may not be detected by either exit or entry screening. Nevertheless, the ability to detect some cases early in the pandemic may slow disease spread even for a short time.

The effective implementation of travel-related containment measures depends on advance planning, preparedness, and coordination at the state, local, federal and international levels. This section provides information on engagement of partners, protocols for managing ill travelers, quarantine preparedness at ports of entry, and legal preparedness.

## 1. Engaging community partners

- In collaboration with the CDC, state and local planning for managing travel-related disease risk during a Pandemic Alert and Pandemic Period might include:
  - Quarantine officers
  - First responders (firefighters, police officers)
  - Local members of the legal community
  - Emergency medical services and other emergency responders
  - Hospital personnel
  - Representatives of airports, seaports, and the transportation industry, including unions
  - Political leaders
  - American Red Cross and other humanitarian organizations
  - Business services
- In collaboration with these partners, state and local health departments should:
  - Develop plans for training, mobilizing, and deploying public health staff and other emergency workers.
  - Conduct exercises and drills at ports of entry.
  - Train healthcare workers and emergency responders in the use of personal protective equipment (PPE) (see Supplement 4).
- State and local health departments should work with quarantine officers to develop memoranda of agreement with hospitals near ports of entry that are equipped to isolate, evaluate, and manage suspected influenza patients (see Supplement 8) and with emergency medical services that can help perform on-site assessments of ill passengers and transport them to hospitals for evaluation.

## 2. Protocols for managing ill travelers at ports of entry

- In collaboration with law enforcement authorities and other partners, public health officials and quarantine officers should develop protocols for managing ill arriving passengers identified by airplane or cruise ship personnel. The protocols should include provisions for:
  - Meeting flights with a reported ill passenger
  - Establishing notification procedures and communication links among organizations involved in the response

- Reporting potential cases to CDC (see **Supplement 1**)
- Providing a medical assessment of the ill traveler and referral for evaluation and care
- Separating the ill traveler from other passengers during the initial medical assessment
- Transporting the ill traveler to a designated healthcare facility (see also **Supplement 8**)
- Identifying other ill passengers and separating them from passengers who are not sick
- Transporting and quarantining contacts, if necessary (see 3 below)
- Enforcing isolation and quarantine, if necessary, when ill travelers or their contacts are uncooperative
- CDC is working with partners in the travel industry to ensure that airplane and cruise ship personnel are familiar with:
  - Case definitions (e.g., symptoms, travel history) for avian influenza A (H5N1) and other novel influenza strains of public health concern as they arise. CDC will provide additional and updated case definitions, as necessary, during the Pandemic Alert and Pandemic Periods.
  - Actions to take and persons to contact at their home offices, local quarantine station, or CDC if they are concerned about a sick passenger who might have novel influenza

### 3. Quarantine preparedness at ports of entry

- State and local public health officials, in collaboration with the CDC should identify quarantine facilities for housing passengers, crew, and emergency workers who may have been exposed to an ill traveler. These facilities should be equipped for:
  - Temporary quarantine (a few days), until the results of diagnostic tests become available
  - Longer-term quarantine (up to 10 days) if a diagnosis of pandemic influenza is confirmed
- State and local health departments and community partners should plan for the provision of goods and services to persons in quarantine (see **Supplement 8**).

### 4. Legal preparedness

While the federal government is primarily responsible for preventing the introduction, transmission, and spread of communicable diseases from foreign countries into the U.S., state and local health authorities may also take measures, such as quarantine of ill travelers and their contacts, to prevent the spread of communicable diseases within their borders. State and local authorities are primarily responsible for restricting travel within their borders while the federal government may take measures to prevent the interstate spread of communicable diseases.

Because jurisdictions and authorities at airports and other ports of entry overlap, local, state, and federal health authorities should establish protocols and outline roles and responsibilities in advance of a public health emergency. To be adequately prepared for management of travel-related risks, state and local health departments should:

- Ensure that legal authorities for the isolation of ill persons and the quarantine of exposed persons (at the local, state, and federal levels) are known and understood (see **Supplement 8**).
- Develop procedures for addressing overlapping multi-jurisdictional issues.

- Ensure legal authorities and develop protocols for:
  - Requirements for pre-departure screening of international and domestic travelers
  - Requirements for arrival screening and/or quarantine of international and domestic travelers
  - Prohibitions on travel by ill persons and their contacts
  - Restrictions on use of mass transit systems
  - Cancellation of nonessential travel
- Work closely with local, state, and federal law enforcement officials to develop plans and protocols for enforcing travel restrictions, if necessary.

## B. Health information for travelers

CDC's Travelers' Health website ([www.cdc.gov/travel/](http://www.cdc.gov/travel/)) will provide up-to-date travel notices for international travelers to countries affected by novel influenza viruses during the Pandemic Alert Period and Pandemic Period. These notices are issued depending on the scope, risk for travelers, and recommended preventive measures. Four types of travel notices can be issued: In the News, Outbreak Notices, Travel Health Precautions, and Travel Health Warnings. Additional Travel Health Precautions or Warnings (see Box 2) may be issued to inbound and outbound travelers during the Pandemic Alert Period if avian influenza spreads internationally and causes additional cases of human influenza.

## C. Evaluation of travel-related cases of infection with novel strains of influenza

During the Pandemic Alert Period, travel-related cases of infection might be detected after entry into the United States or reported during transit by airline or cruise ship personnel before arrival of an ill passenger. Information on the detection and identification of novel strains of influenza is provided in **Supplement 1**. Guidance on the clinical management of suspected cases of novel influenza is provided in **Supplement 5**.

### 1. Managing ill passengers

- State and local health departments should follow protocols prepared in advance for the management of arriving ill passengers who meet the clinical and epidemiologic criteria for infection with a novel strain of influenza. Additional or updated case definitions for infection with novel strains of influenza will be issued, as needed, if the level of heightened surveillance increases from a situation of little immediate pandemic risk (corresponding to WHO Pandemic Alert Phase 3), to one in which pandemic risk is moderate or substantial (corresponding to WHO Pandemic Alert Phases 4 or 5).
- If an ill passenger with a suspected case of novel influenza is reported aboard an arriving airplane or cruise ship, a state or local health official or quarantine officer should do the following:
  - All partners should be notified, including the nearest Quarantine station, state and local authorities, and the CDC.
  - Request information on the ill passenger's symptoms and travel and exposure history to make an initial assessment if the illness meets the current clinical and epidemiologic criteria for avian influenza A (H5N1) or is suspicious for a novel influenza strain.
  - Determine if a state or local public health worker and/or quarantine officer should meet the airplane or cruise ship to further evaluate the ill traveler.
  - Provide the crew with guidance on infection control procedures, if needed (e.g., separate the ill passenger as much as possible from other passengers; provide the ill passenger with a mask or tissues to cover coughs and sneezes).
- If a state or local public health worker and/or quarantine officer decides to meet the airplane or cruise ship and perform an initial medical evaluation of the ill traveler, the passengers and crew should be informed of the situation and should not be allowed to disembark until the evaluation is complete.



- If public health officials determine that the ill passenger meets the clinical and epidemiologic criteria for infection with a novel influenza strain, the patient should be sent by ambulance to a hospital, using appropriate infection control procedures for transit and patient isolation (see Supplement 4).<sup>1</sup>

## 2. Managing travel contacts

- Local and/or state health departments, in consultation with CDC, should decide how to manage an ill person's travel contacts on a case-by-case basis, taking into consideration the following factors:
  - Likelihood that the suspected case is due to a novel influenza strain (based on symptoms and travel history, if laboratory results are not available)
  - Likelihood that the causative virus is transmitted from person to person with a moderate or high efficiency (as in later phases of the Pandemic Alert Period)
  - Feasibility of tracing and monitoring travel contacts, as well as the patient's family members, workmates, schoolmates, and healthcare providers
- Management of contacts might include:
  - Passive or active monitoring without activity restrictions
  - Quarantine at home or in a designated facility, and/or
  - Antiviral prophylaxis or treatment.

For retrospectively identified cases, if passengers and crew members cannot be traced within 48–72 hours of the presumed exposure, local and/or state health departments, in consultation with CDC, might consider other options (e.g., issue a public notice through the news media).

- During the Pandemic Alert Period, especially during the earlier phases, health departments should quarantine travel contacts (i.e., passengers, crew, response workers) **only when there is a high probability that the ill passenger is infected with a novel influenza strain that is transmitted between people.**

If a decision is made to initiate quarantine, persons who cannot be quarantined at home should be housed in a pre-designated temporary care facility until the diagnosis of the ill passenger is confirmed or disproved. Each quarantined person should receive a preliminary medical assessment and should be interviewed to ascertain their travel and exposure histories.

- If the diagnosis of a novel strain of influenza is confirmed, quarantined persons should be transferred as soon as possible to a pre-designated longer-term quarantine facility and should remain there for the maximum length of the incubation period for influenza. Each quarantined person may receive antiviral medication and should be monitored twice a day for fever and other signs of influenza (see Supplement 8).
- Medical follow-up and travel assistance should be provided to all quarantined persons when the quarantine period is over.

## D. Preventing the importation of infected birds and animals

State health departments should continue to assist federal agencies with responsibility for preventing the shipment of infected birds and animals into the United States. Federal agencies with responsibility for inspecting imported animals, implementing veterinary quarantine orders, and enforcing U.S. Department of Agriculture (USDA) trade bans and HHS import bans include

<sup>1</sup> Protocols and memoranda of agreement with ambulance service and hospitals with appropriate infection control measures in place should be established.

the Animal and Plant Health Inspection Service (APHIS), USDA; HHS/CDC; Bureau of Customs and Border Protection, Department of Homeland Security; and U.S. Fish and Wildlife Service, Department of the Interior.

USDA regulates the importation of all avian species (poultry, pet birds, birds exhibited at zoos, ratites) into the United States (9 CFR, Part 93). In general, birds submitted for entry into the United States must be quarantined in USDA-approved facilities. During quarantine, avian influenza virus isolation is attempted on samples collected from all dead birds and some live birds. These precautions are taken to prevent the introduction of exotic avian diseases, including avian influenza, into the United States. USDA import procedures for avian species are provided at [www.aphis.usda.gov/vs/ncie/importing.html](http://www.aphis.usda.gov/vs/ncie/importing.html).

Under section 316 of the PHS Act (42 USC 264) the HHS Secretary may make and enforce regulations necessary to prevent the introduction, transmission, and spread of communicable disease from foreign countries into the U.S. and from one state or possession into any other state or possession. CDC has implemented this statute through regulations and those that authorize CDC's order banning birds and bird products that might carry avian influenza A (H5N1) can be found at 42 CFR 71.32(b). A current listing of CDC's orders banning the importation of birds and bird products that might carry avian influenza A (H5N1) can be found at [www.cdc.gov/flu/avian/outbreaks/embargo.htm](http://www.cdc.gov/flu/avian/outbreaks/embargo.htm).

## **S9-IV. RECOMMENDATIONS FOR THE PANDEMIC PERIOD**

Over the course of an influenza pandemic, state and local health authorities might consider a range of travel-related control measures to decrease the spread of disease into the United States, out of the United States (Appendix 2), or within the United States. The following factors may be considered in developing policy:

- The relative magnitude, duration, and stage of indigenous transmission versus the risk associated with further introduced cases. When pandemic disease is widespread in the U.S., the additional contribution of introduced cases to the magnitude or spread of the pandemic will be minimal depending on the state of the epidemic in the specific location of introduction.
- The value of compulsory restrictions in a setting of voluntary changes in travel patterns. Voluntary changes in travel will occur during a pandemic as persons choose to cancel nonessential travel to decrease their potential exposure and risk of acquiring influenza infection. In this context, the added value of compulsory restrictions should be considered relative to the societal disruptions that limitations on movement would cause.

HHS will promote an active process of engagement and discussion to help states and localities decide on which actions to take as the situation evolves. Because travel-related measures implemented by one jurisdiction will inevitably affect others, communication, collaboration, and especially coordination before any measures are implemented is crucial.

### **A. Travel-related containment measures**

#### **1. Travel into the United States**

Early during an influenza pandemic that begins outside the United States, health authorities will heighten disease surveillance at U.S. airports and seaports and maintain close communication with WHO, foreign governments, and the airline industry. Travel-related disease control measures will include management of ill travelers arriving at ports of entry and provision of travel health alert notices to incoming travelers.

##### **a) Managing arriving ill passengers**

Identification and management of incoming ill travelers may delay and decrease the introduction of novel influenza strains into the United States during the Pandemic Alert Period. These efforts will continue during the early stages of the Pandemic Period, especially if a pandemic strain emerges in another country but has not yet entered the United States.

Once the pandemic has spread outside and within the United States, screening for arriving ill passengers will become less useful and feasible. Although exit-screening of travelers from affected areas ("source control") is likely to be a more effective disease control measure, its effectiveness too will be limited.

To manage arriving ill passengers, public health authorities or quarantine officers should do the following:

- If a suspected case of pandemic influenza is reported aboard an arriving airplane or cruise ship during the early stages of a pandemic, obtain preliminary information about the ill passenger, and advise the captain and crew on patient isolation and infection control.
- If the likelihood of pandemic influenza infection appears high, consider these actions:
  - Notify the airport to mobilize its first responders, and arrange for patient transport and preparation of quarantine facilities.
  - Meet the airplane or cruise ship, perform a medical evaluation of the ill traveler, and assess the risk to public health.
  - Inform the passengers and crew of the situation, and do not allow them to disembark until the evaluation is complete. Procedures for medical management of the patient, passengers, and crew are described in S9-III.C.

#### **b) Travel health precautions and warnings**

As the pandemic spreads from country to country, HHS will update country-specific travel notices and post them on the CDC Travelers' Health website (<http://www.cdc.gov/travel/>). Advisories might include:

- **Travel Health Precautions** that describe steps that can be taken to reduce the risk of infection (e.g., avoiding travel to high-risk settings and communities where transmission is occurring)
- **Travel Health Warnings** that recommend postponement of nonessential travel

#### **c) Travel-related measures at early stages of a pandemic**

When there is limited transmission in other countries and potential for importation of cases into the United States, HHS and state and local health departments might consider the following actions:

- Initiate enhanced disease surveillance at ports of entry.
- Provide guidance on infection control procedures that can be implemented, if needed, on airplanes or ships (e.g., separate the ill passenger from other passengers; provide the ill passenger with a mask or tissues to prevent viral spread via coughing).
- Isolate arriving ill passengers, and quarantine their contacts as necessary.
- Collect information on all arriving passengers if notification is warranted (e.g., for antiviral administration, vaccination, or health monitoring).

#### **d) Travel-related measures at later stages of a pandemic**

If the situation worsens overseas and there is extensive and sustained transmission in other countries, HHS and state and local health departments might consider these actions:

- Distribute travel health alert notices to passengers arriving from affected countries (i.e., countries for which health warnings have been issued).
- Post travel health alert notices in airports (e.g., on posters).

- Arrange with airline industry partners to show videos or public announcements about pandemic influenza on airplanes or cruise ships arriving from affected countries.
- Recommend canceling or limiting nonessential travel to affected countries.
- Collect information on all arriving passengers if notification is warranted (e.g., for antiviral administration, vaccination, or health monitoring).

Decisions regarding the implementation of these actions may depend on how widely the pandemic disease has spread within the U.S.

Other potential control measures might include increasing disease surveillance among passengers arriving from affected countries by visually inspecting travelers as they disembark, screening travelers for fever or other influenza symptoms, or administering questionnaires on possible exposures to influenza (e.g., contacts with influenza patients or visits to high-risk areas). Experience during the 2003 SARS outbreak (Appendix 1) suggests that implementation of these measures—which are highly labor-intensive and of unproven benefit—would be especially burdensome during an influenza pandemic. However, it is possible that the transmissibility of a unique pandemic strain may differ from that of seasonal influenza strains or SARS, warranting consideration of alternative measures.

## 2. Travel out of the United States

If the level of influenza transmission in the United States presents a high risk for exportation of disease, HHS and state and local health authorities should consider the following actions:

- Distribute travel health warnings to outbound passengers who live in or have visited affected parts of the United States.
- Recommend the cancellation of nonessential travel to other countries from ports of entry in affected parts of the United States.
- Implement pre-departure screening (e.g., temperature screening or visual screening) of outbound travelers.

## 3. Travel within the United States

- If the level of influenza transmission in a U.S. area is high and if most other areas have not yet been affected, HHS and state and local health authorities might decide to recommend limiting or canceling nonessential travel to that area or to implement increased disease surveillance measures.
- Other containment measures and travel restrictions to slow disease spread within the United States that might be considered include:
  - Distributing travel health alert notices on domestic flights
  - Isolating ill arriving passengers on domestic flights and quarantining passengers and crew, following protocols developed for international flights (see S9-III.C)
  - Closing mass transit systems (e.g., buses and subways; see [Supplement 8](#))
  - Closing interstate bus and train routes

The potential effectiveness of these measures (see S9-IV) and the feasibility of implementing them should be considered in decision-making.

## **B. De-escalation of travel-related control measures**

Decisions to de-escalate control measures related to international travel will be made in consultation with WHO.

### **1. Outbound passengers**

CDC will downgrade a Travel Health Warning for outbound U.S. passengers to a Travel Health Precaution for a given country or area when there is adequate and regularly updated reporting of surveillance data from the area, and limited or no recent instances of cases in the area.

### **2. Inbound passengers**

On arrival, inbound passengers from areas under a Travel Health Warning should be provided with travel health alert notices. Because it is often difficult to determine passengers' points of origin, it may be more practical to continue providing travel health alert notices until Travel Health Precautions have been lifted for all areas.

CDC will remove a Travel Health Precaution when there is adequate and regularly updated reporting of surveillance data from the area and limited or no recent instances of cases exported from the area.

## **BOX 1. CDC QUARANTINE STATIONS**

CDC operates 18 quarantine stations that are responsible for preventing the introduction of infectious diseases of public health importance into the United States. The stations are located at major international airports in Los Angeles, San Francisco, Seattle, Miami, Honolulu, Chicago (O'Hare), New York City (JFK), Atlanta, Houston, El Paso, and Washington, DC. Each station also covers other ports of entry (airports, seaports, land borders) in the region. The stations' quarantine officers evaluate ill passengers who are identified by flight crews, U.S. Customs Service inspectors, or other Federal Inspection Service<sup>1</sup> personnel. Quarantine inspectors also work with regulatory agencies to inspect imported animals and other cargo ([http://www.cdc.gov/ncidod/dq/quarantine\\_stations.htm](http://www.cdc.gov/ncidod/dq/quarantine_stations.htm)).

Some ports of entry (with and without quarantine stations) have local physicians on call, and HHS has an ongoing program to establish agreements with local hospitals that accept patients referred by quarantine station staff.

---

<sup>1</sup> Federal Inspection Service agencies include the Animal and Plant Health Inspection Service (APHIS/USDA), Centers for Disease Control and Prevention (CDC/HHS), Customs and Border Protection (CBP/DHS), and Food Safety and Inspection Service (FSIS/USDA).

## BOX 2. TRAVEL-RELATED DEFINITIONS

**Travel Notices:** Different types of notices for international travelers. During the 2003 SARS outbreak, CDC issued two types of travel notifications about disease occurrences in specific geographic areas. A travel alert, a lower-level notice, provided information on the outbreak and informed travelers about how to reduce their risk of acquiring infection. When the health risk for travelers was thought to be high, CDC issued a travel advisory recommending against nonessential travel to the area. Travel advisories were intended to reduce the number of travelers to high-risk areas and the risk for spreading disease to other areas. The levels of notification have since been revised to include four types of travel notices: In the News, Outbreak Notice, Travel Health Precautions, and Travel Warnings.

**In the News:** Notification by CDC of an occurrence of a disease of public health significance affecting a traveler or travel destination. The purpose is to provide information to travelers, Americans living abroad, and healthcare providers. "In the News" is issued when the risk for disease exposure is not increased beyond the usual baseline risk for that area, and only standard guidelines are recommended.

**Outbreak Notice:** Notification by CDC that an outbreak of a disease is occurring in a limited geographic area or setting. The purpose is to provide information to travelers, Americans living abroad, and healthcare providers about the status of the outbreak and to remind travelers about standard or enhanced travel recommendations for the area. Outbreak Notices are issued when the risk for disease exposure is increased but well defined and limited to specific settings.

**Travel Health Precaution:** Notification by CDC that a disease outbreak of significant scope is occurring in a large geographic area. The purpose is to provide information to travelers, Americans living abroad, and healthcare providers about the status of the outbreak (its magnitude, scope, and rapidity of spread), specific precautions to reduce the risk of infection, and what actions to take if they become ill. Travel Health Precautions are issued when the risk for the individual traveler is increased in defined settings or associated with specific risk factors (e.g., transmission in a healthcare or hospital setting). Travel Health Precautions do NOT recommend canceling travel to the area.

**Travel Health Warning:** Notification by CDC that a widespread outbreak of a disease of public health concern is expanding outside the area or populations that were initially affected. The purpose is to provide information to travelers, Americans living abroad, and healthcare providers about the status of the outbreak (its magnitude, scope, and rapidity of spread), specific precautions to reduce the risk of infection, and what actions to take if they become ill. **Travel Health Warnings recommend canceling nonessential travel to the area** because the risk for the traveler is considered high (i.e., there is evidence of transmission outside defined settings and/or inadequate containment). Additional preventive measures may be recommended, depending on the circumstances (e.g., travelers may be requested to monitor their health for a certain period after their return; arriving passengers may be screened at ports of entry). A Travel Health Warning may reduce the volume of traffic to an affected area, which in turn can reduce the risk of disease spread to previously unaffected sites.

**Travel Health Alert Notice:** Notice with travel-related information and recommendations designed for inbound travelers.

**Travel contact:** A person on the same conveyance as the ill person.

**Close contact:** A person who has cared for or lived with the ill person or had a high likelihood of direct contact with respiratory secretions and/or body fluids of the ill person. Examples of close contact with an ill person include kissing or hugging, sharing eating or drinking utensils, talking within 3 feet, and direct touching. Close contact does not include activities such as walking by a person or briefly sitting across a waiting room or office.



## **APPENDIX 1. RECENT EXPERIENCE WITH TRAVEL-RELATED CONTAINMENT MEASURES: THE 2003 SARS OUTBREAK**

During the 2003 global response to severe acute respiratory syndrome (SARS), the control strategy for the United States included issuing travel notifications, distributing Travel Health Alert Notices to travelers arriving from areas with SARS, and conducting visual inspections of arriving travelers to facilitate early identification of imported cases and response to reports of ill passengers. CDC staff met more than 11,000 direct and indirect flights from SARS-affected areas and distributed more than 2.7 million Travel Health Alert Notices to arriving passengers as well as to persons arriving at 13 U.S. land border crossings near Toronto and departing passengers bound for the United States from the Toronto airport. Travel Health Alert Notices informed returning travelers of potential exposure to SARS-associated coronavirus (SARS-CoV). They alerted travelers to the symptoms of SARS-CoV disease and advised them to promptly seek medical attention if symptoms developed. The notices also provided information and instructions for physicians.

During the SARS outbreak response, CDC quarantine staff met planes reporting an ill passenger to facilitate 1) evaluation of the passenger for possible SARS-CoV disease, 2) collection of locating information on the other passengers, and 3) coordination with federal and local authorities. If the ill passenger was determined to be a possible SARS case, the locating information was forwarded to state and local health departments for contact tracing.

Border and travel-related activities implemented in countries more seriously affected by SARS included pre-departure temperature and symptom screening, arrival screening (asking passengers about travel history and possible exposure to SARS-CoV), "stop lists" (maintaining lists of persons who were possible SARS cases or contacts to prevent them from traveling), and quarantine of travelers returning from other SARS-affected areas.

Lessons learned from this response include the following:

- SARS-CoV can spread rapidly on a global scale through international travel if control measures are not implemented.
- SARS-CoV transmission can be halted through aggressive global measures to educate, detect cases early, effectively isolate cases, and identify, monitor, and quarantine contacts.
- Patients with SARS can transmit infection to other passengers on conveyances and should postpone travel until they are no longer infectious.
- SARS-CoV transmission can occur within the close confines of conveyances. Resulting infections usually represent a failure to recognize symptomatic index cases and their high-risk contacts who should have been prevented from traveling.
- Active follow-up of passengers on conveyances with SARS cases can help prevent further spread by informing passengers of their exposure and providing instructions for monitoring their health and seeking medical evaluation if they become ill.

While these lessons may have some relevance, their applicability to an influenza pandemic is limited by the substantial differences between the epidemiology of transmission of influenza and SARS-CoV. The much shorter incubation period and intergenerational period for influenza compared with SARS-CoV poses enormous time challenges to case isolation, contact tracing, and selective individual quarantine. The possibility of influenza virus transmission by asymptomatic persons makes the ability to effectively implement control measures such as selective quarantine necessarily incomplete and potentially decreases the impact significantly. In addition, with SARS-CoV, peak communicability occurred most often during the second week of illness when cases were extremely ill and often hospitalized; this enabled containment to focus heavily on institutional infection control measures. Influenza virus transmission will occur much earlier in relation to illness onset and is expected to

be preferentially community-acquired rather than nosocomial. Finally, there were fewer than 10,000 documented human cases of SARS worldwide whereas past influenza pandemics have caused symptomatic infection in about 30% of the U.S. population. Thus, in the current U.S. population alone there would be almost 90 million illnesses, and many more persons would have asymptomatic infections. Given the vastly greater number of persons who will be spreading influenza infection within and between communities, approaches to control will inevitably need to be different.

## APPENDIX 2. TRAVEL-RELATED INFLUENZA RESPONSE MATRICES

### Matrix 1: Inbound Travel

| Level of influenza transmission                                                                                                                                                        | Suggested actions to manage inbound travel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Potential for imported cases in the United States and limited transmission (clusters of human-to-human cases or second-generation spread) in the inbound traveler's location of origin | <p>CDC will distribute travel health alert notices to all arrivals.</p> <p><b>Suggested actions:</b></p> <ul style="list-style-type: none"> <li>• Consider enhanced disease surveillance at ports of entry.</li> <li>• Request information on the ill passenger's symptoms and travel and exposure histories.</li> <li>• Determine if a state or local public health worker and/or CDC quarantine officer should meet the airplane or cruise ship to further evaluate the ill traveler.</li> <li>• Provide the crew with guidance on infection control procedures, if needed (e.g., separate the ill passenger as much as possible from other passengers; provide the ill passenger with a mask or tissues to prevent viral spread via coughing).</li> <li>• Isolate arriving ill passengers, and quarantine their contacts, as necessary.</li> </ul> |
| Imported cases in the United States and extensive transmission in the inbound traveler's location of origin                                                                            | <p><b>Additional actions:</b></p> <ul style="list-style-type: none"> <li>• Consider prohibiting all nonessential arrivals.</li> <li>• Consider active monitoring of all arriving passengers for fever and respiratory symptoms.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Extensive transmission in the inbound traveler's location of origin                                                                                                                    | <p><b>Additional actions:</b></p> <ul style="list-style-type: none"> <li>• Prohibit all nonessential arrivals.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

## APPENDIX 2. TRAVEL-RELATED INFLUENZA RESPONSE MATRICES (CONT.)

### Matrix 2: Outbound Travel

| Level of influenza transmission                                                                                            | Suggested actions to manage outbound travel                                                                                                                                                                                                                                                           |
|----------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Limited transmission (clusters of human-to-human cases or second-generation spread) in the outbound traveler's destination | <p>CDC will issue Travel Health Precautions and Travel Health Warnings for particular destinations, as needed.</p> <p><b>Suggested actions:</b></p> <ul style="list-style-type: none"> <li>• Distribute targeted health education messages to outbound travelers.</li> </ul>                          |
| Extensive transmission in the outbound traveler's destination                                                              | <p><b>Additional actions:</b></p> <ul style="list-style-type: none"> <li>• Arrange with airline industry partners to show videos or air public announcements about pandemic influenza on airplanes and cruise ships.</li> <li>• Cancel or limit nonessential travel to affected countries.</li> </ul> |
| Extensive transmission in the outbound traveler's destination and in the United States.                                    | <p><b>Additional actions:</b></p> <ul style="list-style-type: none"> <li>• Consider implementing medical screening at exit points in the United States.</li> </ul>                                                                                                                                    |





# **supplement 10** **public health communications**

## **TABLE OF CONTENTS**

|                                                                                                                                                             |        |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|
| SUMMARY OF PUBLIC HEALTH ROLES AND RESPONSIBILITIES IN PUBLIC HEALTH COMMUNICATIONS.....                                                                    | S10-2  |
| S10-I. RATIONALE.....                                                                                                                                       | S10-3  |
| S10-II. OVERVIEW.....                                                                                                                                       | S10-4  |
| S10-III. RECOMMENDATIONS FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS ..                                                                                | S10-4  |
| A. Assessing communications capacity and needs.....                                                                                                         | S10-5  |
| 1. Capacity.....                                                                                                                                            | S10-5  |
| 2. Needs.....                                                                                                                                               | S10-5  |
| B. Conducting collaborative planning .....                                                                                                                  | S10-5  |
| C. Developing and testing standard state and local procedures for disseminating information.....                                                            | S10-6  |
| D. Developing, testing, and disseminating locally tailored Interpandemic messages and materials .....                                                       | S10-7  |
| S10-IV. RECOMMENDATIONS FOR THE PANDEMIC PERIOD .....                                                                                                       | S10-8  |
| A. Activating emergency communications plans .....                                                                                                          | S10-9  |
| B. Refining and delivering messages.....                                                                                                                    | S10-9  |
| C. Providing timely, accurate information.....                                                                                                              | S10-9  |
| D. Providing coordinated communications leadership across jurisdictional tiers (e.g., local, regional, state, and national) .....                           | S10-10 |
| E. Promptly addressing rumors, misperceptions, stigmatization, and unrealistic expectations about the capacity of public and private health providers ..... | S10-10 |
| Appendix 1. Background Information for Developing Communications Messages about Pandemic Influenza .....                                                    | S10-11 |
| Appendix 2. Sample Materials.....                                                                                                                           | S10-12 |
| Appendix 3. Additional Resources.....                                                                                                                       | S10-13 |
| Appendix 4. HHS Pandemic Influenza Risk Communication and Public Outreach Strategy .....                                                                    | S10-15 |

## **SUMMARY SUMMARY OF PUBLIC HEALTH ROLES AND RESPONSIBILITIES IN PUBLIC HEALTH COMMUNICATIONS**

### **INTERPANDEMIC AND PANDEMIC PERIODS**

#### **State and local responsibilities:**

- Assess and monitor readiness to meet communications needs in preparation for an influenza pandemic, including regular review and update of communications plans.
- Plan and coordinate emergency communication activities with private industry, education, and nonprofit partners (e.g., local American Red Cross chapters).
- Identify and train lead subject-specific spokespersons.
- Provide public health communications staff with training on risk communications for use during an influenza pandemic.
- Develop and maintain up-to-date communications contacts.
- Participate in tabletop exercises and other collaborative preparations to assess readiness.
- Address rumors and false reports regarding pandemic influenza threats.
- Confirm any contingency contracts needed for communications resources during a pandemic

#### **HHS responsibilities:**

- Develop a Communications and Public Engagement Strategy for Pandemic Influenza (see appendix 4)
- Develop key messages and materials, conduct audience research and message testing, and share results with international, other Federal departments, state and local communications staff. Materials will be available on [www.pandemicflu.gov](http://www.pandemicflu.gov).
- Coordinate pandemic influenza media messages to ensure consistency.
- Provide tools and resources through the [www.pandemicflu.gov](http://www.pandemicflu.gov) and [www.cdc.gov/flu/](http://www.cdc.gov/flu/) websites and other avenues to help educate state and local communications staff.
- Identify and train lead spokespersons.
- Provide state and local health agencies with guidance about developing and integrating communications aspects of preparedness plans.
- Work with state and local governments to incorporate communications preparedness as part of larger preparedness exercises.
- Provide regular updates about situations that pose potential pandemic influenza threats (e.g., through Health Alert Network [HAN] notices, Epi-X, and web postings).
- Distribute educational messages and materials about pandemic influenza and ways that people can protect themselves and their families.
- Distribute practical information, such as travel advisories, infection control measures, availability and appropriate use of antiviral medications and vaccines, and specific public health actions that may be advised.
- Address rumors and false reports regarding pandemic influenza threats and related issues.
- Coordinate international information exchange and communication strategies with WHO and other international partners, as appropriate.



## **SUMMARY OF PUBLIC HEALTH ROLES AND RESPONSIBILITIES (CONT.) IN PUBLIC HEALTH COMMUNICATIONS**

### **PANDEMIC PERIOD**

#### **State and local responsibilities:**

- Contact key community partners and implement frequent update briefings.
- As appropriate, implement and maintain community resources, such as hotlines and websites to respond to local questions from the public and professional groups.
- Tailor communications services and key messages to specific local audiences.
- In coordination with epidemiologic and medical personnel, obtain and track information daily on the numbers and location of newly hospitalized cases, newly quarantined persons, and hospitals with pandemic influenza cases. Use these reports to determine priorities among community outreach and education efforts, and to prepare for updates to media organizations in coordination with federal partners.

#### **HHS responsibilities:**

- Coordinate pandemic influenza media messages to ensure consistency across Federal government
- Coordinate communications activities with state and local communications staff, including regional or local communications centers as appropriate.
- Promptly respond to rumors and inaccurate information to minimize concern, social disruption, and stigmatization.
- Coordinate international information exchange and communication strategies

## **S10-I. RATIONALE**

Strategic communications activities based on scientifically derived risk communications principles are an integral part of a comprehensive public health response before, during, and after an influenza pandemic. Effective communication guides the public, the news media, healthcare providers, and other groups in responding appropriately to outbreak situations and complying with public health measures.

The goals of **Supplement 10** are to:

- Describe the integral role of communications in preparing for, implementing, and evaluating public health actions to protect health and prevent pandemic influenza-associated morbidity and mortality.
- Provide local and state health officials, community healthcare professionals and communications specialists with guidance to assist them in developing and implementing communication plans that support an effective public health response and help minimize anxiety, fear, and stigmatization.
- Provide the basis for a well-coordinated and consistent communications strategy across jurisdictions, based on a common adherence to established risk communication principles.

This supplement emphasizes the following strategies to help state and local communications professionals collaborate with each other, CDC, and other organizations to accomplish these goals:

- Provide timely, accurate, consistent, and appropriate information about pandemic influenza public health interventions.
- Emphasize the rationale and importance of adherence to public health measures that some people may consider intrusive (e.g., quarantine).
- Help set realistic expectations of public health and health care systems.
- Promptly address rumors, inaccuracies, and misperceptions.
- Minimize stigmatization that may occur during a pandemic.
- Adapt materials for others with special needs (e.g., non-English speaking populations, difficult-to-reach communities, and persons living in institutional settings) receive appropriate information.
- Acknowledge the anxiety, distress, and grief that people experience during long-term, major public health events such as pandemics.

## **S10-II. OVERVIEW**

Communications preparedness for an influenza pandemic, as outlined in this supplement, follows seven key risk communications concepts.

- When health risks are uncertain, as likely will be the case during an influenza pandemic, people need information about what is known and unknown, as well as interim guidance to formulate decisions to help protect their health and the health of others.
- Coordination of message development and release of information among federal, state, and local health officials is critical to help avoid confusion that can undermine public trust, raise fear and anxiety, and impede response measures.
- Guidance to community members about how to protect themselves and their family members and colleagues is an essential component of crisis management.
- Information provided to the public should be technically correct and succinct without seeming patronizing.
- Information presented during an influenza pandemic should minimize speculation and avoid over-interpretation of data, overly confident assessments of investigations and control measures.
- An influenza pandemic will generate immediate, intense, and sustained demand for information from the public, healthcare providers, policy makers, and news media. Healthcare workers and public health staff are likely to be involved in media relations and public health communications.
- Timely and transparent dissemination of accurate, science-based information about pandemic influenza and the progress of the response can build public trust and confidence.

During the Interpandemic Period, national, state, and local health communications professionals should focus on preparedness planning and on building flexible, sustainable communications networks. During the Pandemic Period, they should focus on well coordinated health communications to support public health interventions designed to help limit influenza-associated morbidity and mortality.

## **S10-III. RECOMMENDATIONS FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS**

During the Interpandemic and Pandemic Alert Periods, health communications professionals should work together to develop and maintain communications preparedness and to keep the public and other target groups updated about risks as the threat of a pandemic evolves. Actions fall into four major categories:

- Assessing communications capacity and needs
- Conducting collaborative planning
- Developing and testing standard procedures for disseminating information
- Developing, testing, and disseminating locally tailored messages and materials

## A. Assessing communications capacity and needs

A first step in effective risk communications preparedness is to conduct an assessment of communications strengths and challenges. Planning should include the following.

### 1. Capacity

- As part of overall pandemic influenza preparedness planning, develop a phased risk communications plan.
- Determine whether adequate human and fiscal resources will be available for all phases of a pandemic. If not, plan to augment these resources.
- Review or establish procedures to help ensure that technology such as networks, servers, and system backups are available, periodically tested, and integrated into overall planning for pandemic influenza. Identify and include other types of technology, such as faxes and mass mailing systems. Establish priorities and implement improvement plans for any technology deficiencies.
- Prepare for resource contingencies (e.g., surge capacity) by developing and regularly updating backup plans and procedures, identifying community resources, and training extra staff for emergency communications responsibilities.
- Ensure ongoing proficiency among all staff engaged in pandemic influenza response, especially given personnel changes, reorganization, or other variables.

### 2. Needs

- Review and update risk communications plans at least annually to ensure that they remain practical and evidence-based. Share the plans in advance with stakeholders.
- Identify communications professionals and media spokespersons; as needed, provide media training and instruction in crisis and risk communication. Encourage familiarity with professional counterparts from local/regional jurisdictions or communities to facilitate collaboration.
- Familiarize key officials with available communications resources and gaps; apprise policy and key decision-makers of plans to deploy staff and resources during an influenza pandemic.
- Prepare basic communications resources in advance, and plan to update them during a pandemic. Appendices 2 and 3 provide sample templates, fact sheets, and other communications tools that will be available through the [www.pandemicflu.gov](http://www.pandemicflu.gov) and [www.cdc.gov](http://www.cdc.gov) websites, as well as links to other resources.
- Identify common communications opportunities or challenges with neighboring jurisdictions, particularly with regard to reaching people in high-priority risk groups; consider novel opportunities to pool communications resources.
- Continuously monitor the effectiveness of risk communication activities, adjusting as necessary to achieve public health communications objectives.

## B. Conducting collaborative planning

Collaborative planning should begin as early as possible. Communications professionals in the public and private sectors need to ensure strong and well-integrated working relationships that will help sustain communications resources as a pandemic evolves. Federal interaction with WHO and other international partners is vital to surveillance and other essential information

exchange and to building collaborative and consistent messaging strategy. The following recommendations are critical elements of a comprehensive domestic response:

- When appropriate, coordinate training and other preparedness activities that include options for backing up key communications personnel in the event of their personal illness or emergency.
- Coordinate with partner agencies to prepare for appropriate public, healthcare provider, policy, and media responses to outbreaks of pandemic influenza. Be prepared to address the following topics as a pandemic alert draws near:
  - Basic health protection information the public and other target audiences will need
  - Responsiveness, capabilities, and limitations of the public health system
  - Roles and responsibilities of diverse pandemic response stakeholders
  - Resources to help people cope with escalating fear, anxiety, grief, and other emotions (see **Supplement 11**).
  - How public health procedures and actions may change during different pandemic phases and why unusual steps may be needed to protect public health.
- Consider when and how to use federal assistance when available. For instance, background information and frequent updates for communications and other healthcare professionals will be available on the [www.pandemicflu.gov](http://www.pandemicflu.gov) website and through other official mechanisms.
- Identify and engage credible local resources as partners. For example, local chapters of nonprofit health organizations may assist with urgent communications to community groups.
- Affirm mechanisms with news media representatives to optimize effective working relationships during pandemic phases.
- Ensure that communications professionals have opportunities to participate with other public health and emergency staff in tabletop exercises and drills to help identify and resolve potential problems in the Interpandemic and Pandemic Alert periods.

## C. Developing and testing standard state and local procedures for disseminating information

Although there will be much that is unpredictable about an influenza pandemic, communication processes can and should be formalized. Standard, yet flexible procedures for disseminating information support consistency, efficiency, and coordination, and improve prospects for effective feedback in both internal and external communications.

State and local communication plans should identify dissemination procedures and channels for forwarding communications from federal agencies to ensure that partners and stakeholders at all levels remain informed but protected from redundant or unnecessary messaging. As an influenza pandemic unfolds, HHS and its agencies will relate essential information through well established channels and formats (e.g., CDC's Emergency Communication System).

The following recommendations can aid development of effective state and local information dissemination plans for use during an influenza pandemic:

- Establish expedited procedures for reviewing and approving pandemic influenza-related messages and materials.
- Establish protocols for frequently updated information, including daily disease activity reports. These may include morbidity and mortality figures, geographic location of cases, demographics of infected populations, and the number of persons hospitalized.
- Establish and maintain a website with current information.
- Work with local information technology (IT) professionals to identify development servers on which to build state or local emergency websites that can help manage information requests when needed. Consider whether to develop some

communications materials in advance and store them on these secure servers. Add the [www.pandemicflu.gov](http://www.pandemicflu.gov) website as a link to local websites. Also see other available links in Appendix 3.

- Federal hotlines, such as the CDC-INFO telephone line (1-800-CDC-INFO; 1-800-232-4636), will be available for public information. However, during an influenza pandemic, state and local health departments may also wish to tailor additional information for their localities. Determine if agreements or contracts will be needed to establish a local toll-free public information hotline. Hotline staff should be trained in advance. They should have access to the [www.pandemicflu.gov](http://www.pandemicflu.gov) website and to an evolving state or local database of frequently asked questions. Consider options for adapting existing networks into pandemic influenza response systems, either singularly or in combination with neighboring jurisdictions.
- Prepare contingency plans to manage increased media demands. Jurisdictions with possible or early confirmed cases of pandemic influenza can expect focused media attention. Local media relations specialists will need to prepare for media requests and facilities needs, especially for television. Regularly scheduled press briefings may reduce the volume of inquiries to press offices. Media interest may merit daily briefings.
- Develop ongoing coordination procedures with other agencies and organizations to conserve resources and avoid duplication in such areas as developing and pre-testing messages, and in training media spokespersons.

## **D. Developing, testing, and disseminating locally tailored Interpandemic messages and materials**

The Interpandemic period is the ideal time to identify and learn about target audiences and raise awareness and knowledge of pandemic influenza. Doing so, however, may prove challenging. For instance, in the absence of pandemic influenza, it may be difficult to generate media and public interest in pandemic influenza. In addition, the need to inform and educate the public, healthcare professionals, policy-makers, and others about the threat of a pandemic must be balanced against the possibility that a pandemic may not occur for many years and may or may not be severe. Risk communication strategies such as dilemma-sharing and acknowledging uncertainty can help establish appropriate and balanced messages.

It is also appropriate during the Interpandemic Period to prepare communications materials for use during the Pandemic Alert and Pandemic Periods. Advance message development helps to ensure that the target audience's questions and concerns are addressed and that messages are credible and understandable. Answers to the most likely questions can be provided by way of press releases and fact sheets, using "place-holders" for specific details to be inserted later. Reviewing and clearing these materials in advance can help identify potential areas of disagreement and allow time to work through controversies outside the stressful environment of an emergency response. Formative research can help inform development of appropriately tailored messages. (See Appendices 1 and 2 for additional information about message development.)

Communications efforts should also take into account knowledge, attitudes, and beliefs (KABs) that suggest how audiences understand and react to certain messages. Concerns will vary by group or subgroup but will likely include personal safety, family and pet safety, and interruption of routine life activities. State and local communications professionals should identify methods to assess the unique KABs of target audiences in their populations and communities. Such activities can help identify potential barriers to compliance with response measures, and inform message development to build support and trust.

Stigmatization and discrimination (e.g., being shunned as a perceived source of contagion) can be especially difficult and potentially dangerous during an infectious disease outbreak. Identify possible scenarios when stigmatization may occur. Plan steps to address and resolve such problems quickly and repeatedly if needed. Consider messages for general audiences, high-risk groups, and difficult-to-reach populations. (For additional information, see Supplement 11, which includes sections on psychosocial factors and issues.)

Basic human needs for self-protection and protection of loved ones can have both positive and negative impacts on public health efforts. Stress, worry, and fear will be present to varying degrees throughout a pandemic. Communications professionals

should work ahead of time with others—including mental health experts—to assess the effect of message content on public anxiety, anticipate other possible stressful situations, and plan appropriate countermeasures.

Additional considerations for developing and disseminating messages and materials about pandemic influenza include the following:

- Assess existing organizational resources for communications, including materials and messages to meet concerns and information needs of target audiences and identify current and potential information gaps.
- Maintain current, accessible, and secure communications contact lists and databases.
- Develop a portfolio of communications information sources, including material on topics such as clinical and laboratory diagnostics, infection control practices, isolation and quarantine procedures, stigmatization management, travel control authority, and legal issues related to the pandemic. States and localities will find much information for a portfolio through the [www.pandemicflu.gov](http://www.pandemicflu.gov) website and other resources during a pandemic and are encouraged to use or adapt these materials.
- Work with local subject-matter experts to adapt key national messages about topics such as basic medical treatments, prioritization recommendations for high-risk groups, use of antiviral medications, and access to care. HHS will provide communications materials (e.g., fact sheets, question-and-answer documents, and message maps) for states and localities to use and adapt.
- Work with local subject-matter experts to adapt communications components of education courses and materials in multiple formats for professional audiences. Consult the [www.pandemicflu.gov](http://www.pandemicflu.gov) and [www.cdc.gov/flu/](http://www.cdc.gov/flu/) websites for information about specific materials and training opportunities.
- Develop a specific, consistent plan to identify and address rumors and misinformation promptly. Test the plan before a pandemic occurs and modify as needed to ensure it works.
- Identify preferred channels for target audiences. For example, many healthcare providers will have no experience with an influenza pandemic and will rely in part on state and local health departments for rapid access to information.
- Ensure the availability of communications products in multiple languages, based on the demographics of the jurisdiction. Health departments may choose to use or adapt translated materials that will be available on the [www.pandemicflu.gov](http://www.pandemicflu.gov) and [www.cdc.gov/flu/](http://www.cdc.gov/flu/) websites. Test key messages with local target audiences and revise them as needed. CDC will engage in message and materials testing activities and share the results broadly through websites and via the National Public Health Information Coalition (NPHIC).
- Begin disseminating messages and materials to increase the knowledge and understanding of the public, healthcare professionals, policy-makers, media, and others about unique aspects of pandemic influenza that distinguish it from seasonal influenza, and generally what to expect during different phases of an influenza pandemic.
- Provide coordinated information on ways to access help (e.g., hotlines, helplines) and self-help (e.g., psychological resources, and stress and anxiety management).

## S10-IV. RECOMMENDATIONS FOR THE PANDEMIC PERIOD

HHS will coordinate international information exchange and the coordination of messaging through WHO and other international partners, as appropriate. Domestic health communications, including state and local public health communications efforts, should be directed to rapid sharing of appropriate, up-to-date information on what is known and what is unknown about the progression of the outbreak, the possible disruptions to routines and events, and contingency measures. Consistency in messaging across jurisdictions is strongly advised.

The Pandemic Period is likely to last much longer than a typical influenza season and may occur in waves within communities. During this period, watch especially for challenges that may arise with staff fatigue or absenteeism due to illness, difficulties with continuity of services, and problems associated with institutional memory that may occur with high staff turnover. Communications staff and others may need to modify plans made during the Interpandemic and Pandemic Alert Periods.

Primary areas on which communications professionals should focus during the Pandemic Period are providing timely, accurate information in especially challenging conditions, coordinating communications leadership across all tiers of jurisdiction (e.g., local, state, regional, and national), and promptly addressing rumors, misperceptions, stigmatization, and any unrealistic expectations about public and private health provider response capacity.

## **A. Activating emergency communications plans**

Consider the context of the local situation when making decisions to activate formal emergency communication systems at the state and local levels. State and local health departments may want to consider potential thresholds and triggers that might indicate that communications demands are likely to escalate quickly. These might include developments that raise the health risk to local populations (for example, if a human case of avian influenza is reported in a local jurisdiction). As communications demands escalate, state and local health departments may want to activate emergency communications plans, including local toll-free information hotlines and an emergency communications website with links to the [www.pandemicflu.gov](http://www.pandemicflu.gov) website.

## **B. Refining and delivering messages**

The following are steps for states and local areas to consider, in collaboration with federal partners:

- Provide regular updates and offer opportunities to address questions (e.g., in partnership with news media, in public forums, and in printed or electronic messages).
- Distribute practical information, such as travelers' advisories, infection control measures, and information about potential priority distribution of antiviral medications and first-generation vaccines. Be prepared to immediately address questions related to initial case(s) and to provide guidance to the public about disease susceptibility, diagnosis, and management, as well as other topics.
- Reinforce and verify ways to help people protect themselves, their families, and others, including self-care information for psychological well-being.
- Address rumors and misinformation promptly and persistently.
- Take steps to minimize stigmatization.

## **C. Providing timely, accurate information**

Depending on health, economic, and overall societal effects, such as the extent of influenza-related illness and death, communications professionals should reassess and adjust as necessary to emerging needs and expectations of public and professional audiences. Areas meriting particular attention include:

- Community subject-matter experts and spokespersons. It may be important to consider additional recruitment and training.
- Effectiveness of procedures for keeping communications lists, materials, and databases current and accurate.
- Open and accessible channels for advice to the public, including ongoing functioning of hotlines in collaboration with the CDC-INFO telephone line. In addition to providing ready access to inquiries and concerns, state and local hotlines can help communications professionals assess community awareness and behaviors and adapt communications strategies.



## **D. Providing coordinated communications leadership across jurisdictional tiers (e.g., local, regional, state, and national)**

- Work with state and local officials to involve communications professionals on senior leadership teams, including roles as liaisons to national communications teams at CDC and other agencies as necessary.
- Maintain strong working relationships with colleagues in other jurisdictions and regions, even when an outbreak may not yet have affected your area directly or may have subsided locally. The following colleagues are especially important to consider.
  - Public affairs directors and information officers from other local and state health departments
  - City and state government public affairs officers
  - Communications staff at congressional and other government offices
  - Communications staff at local and regional police, fire, and emergency management offices
  - Regional health and emergency preparedness colleagues
  - State and local mental health agencies
  - Hospital public relations/affairs departments
  - State and local Emergency Operations Center coordinators
  - Federal Emergency Operations Centers
- Promote public acceptance and support for national response measures and contingency plans.

## **E. Promptly addressing rumors, misperceptions, stigmatization, and unrealistic expectations about the capacity of public and private health providers**

After the initial stages of a pandemic, news media coverage may become more mixed, with both positive and critical coverage. Hero stories may emerge, while "what ifs" and negative images may start to compete for the public attention. As the media proceeds into in-depth analysis of what happened and why, these elements become important to an effective response:

- Monitor news media reports and public inquiries to identify emerging issues, rumors, and misperceptions and respond accordingly.
- Conduct "desk-side briefings" and editorial roundtables with news media decision-makers.
- Proactively address groups that voice overly critical, unrealistic expectations.
- Establish trust with marginalized groups subject to or experiencing stigmatization and cite specific media outlets for inaccurate, misleading, or misguided reporting that may serve to encourage stigmatization.
- Maintain scheduled access to pandemic subject-matter experts to balance the media's needs with other subject-matter expert priorities.

## APPENDIX 1. BACKGROUND INFORMATION FOR DEVELOPING COMMUNICATIONS MESSAGES ABOUT PANDEMIC INFLUENZA

The language, timing, and detail of key messages will depend on a number of factors, including demographics and group psychological profiles of intended audiences, available or preferred media, and urgency. However, the following points may help communications professionals adapt appropriate health messages related to an influenza pandemic:

- By definition, pandemic influenza will result from a new influenza A subtype against which humans have limited or no natural immunity. Pandemic influenza virus infection therefore is likely to cause serious, possibly life-threatening disease in greater numbers, even among previously healthy persons, than occurs during seasonal inter-pandemic influenza outbreaks.
- Global influenza pandemics are unpredictable events, presenting challenges for communication..
- Global and domestic surveillance, coupled with laboratory testing, are vital to identifying new influenza A subtypes virus strains with pandemic potential.
- The threat of a pandemic may be heightened when a highly pathogenic avian influenza A virus spreads widely among birds and infects other animals, including humans. The strains can mutate or adapt and give rise to a strain that spreads easily from person to person in a sustained manner, causing a pandemic.
- Illness and death may be much higher during a pandemic than during annual seasonal community influenza outbreaks; pandemics can also occur in waves over several months.
- It could take many months to develop an effective pandemic influenza vaccine and immunize substantial numbers of people. Antiviral medications for treatment or prevention of pandemic influenza could have an important interim role, but may also be in short supply. Consequently, practical and common sense measures, such as frequent handwashing, covering your mouth and nose while sneezing or coughing, and staying home from work or school if you are ill with influenza-like illness, may be important to help prevent the spread of pandemic influenza.
- Although travel restrictions and isolation and quarantine procedures may limit or slow the spread of pandemic influenza in its earliest stages, these measures are likely to be much less effective once the pandemic is widespread. Alternative population containment measures (e.g., cancellation of public events) may be necessary.
- The United States is preparing for pandemic influenza by:
  - Developing a coordinated national strategy to prepare for and respond to an influenza pandemic
  - Educating healthcare workers about pandemic influenza diagnosis, case management, and infection control practices
  - Refining global and domestic pandemic influenza surveillance systems
  - Developing guidelines for minimizing transmission opportunities in different settings
  - Expanding supplies of antiviral medications in the Strategic National Stockpile and establishing guidelines for their use
  - Developing candidate vaccines and establishing plans for the rapid development, testing, production, and distribution of vaccines that may target specific pandemic influenza strains
  - Developing materials that states and localities can adapt as guidance for use during an influenza pandemic.

## APPENDIX 2. SAMPLE MATERIALS

HHS will provide communications materials for states and localities throughout all pandemic phases. Many of these resources will be made available at appropriate times on the [www.pandemicflu.gov](http://www.pandemicflu.gov) website. Others will be disseminated by using the Health Alert Network (HAN), Epidemic Information Exchange (Epi-X), and other resources for health professionals. The following list offers a sample of the types of communications materials that states and local areas can expect from CDC. This is not an inclusive list and may change depending on the nature and circumstances of a specific influenza pandemic threat. See Appendix 3 (of this supplement) for additional resources.

Pandemic Influenza Fact Sheet

<http://www.cdc.gov/flu/avian/gen-info/pandemics.htm>

Avian Influenza Fact Sheet

<http://www.cdc.gov/flu/avian/gen-info/facts.htm>

Guidance to Travelers

[http://www.cdc.gov/travel/other/avian\\_flu\\_ah5n1\\_031605.htm](http://www.cdc.gov/travel/other/avian_flu_ah5n1_031605.htm)

Interim Guidance for U.S. Citizens Living Abroad

[http://www.cdc.gov/travel/other/avian\\_flu\\_ig\\_americans\\_abroad\\_032405.htm](http://www.cdc.gov/travel/other/avian_flu_ig_americans_abroad_032405.htm)

Sample CDC News Conference Transcript

<http://www.cdc.gov/od/oc/media/transcripts/t040127.htm>

Managing Anxiety in Times of Crisis

<http://mentalhealth.samhsa.gov/cmhs/managinganxiety/default.asp>

## APPENDIX 3. ADDITIONAL RESOURCES

HHS and its agencies will make resources available to state and local health professionals to assist with their communications responsibilities during Interpandemic, Pandemic Alert, and Pandemic Periods. Because information may change frequently, check the [www.pandemicflu.gov](http://www.pandemicflu.gov) and [www.cdc.gov/flu/](http://www.cdc.gov/flu/) websites for up-to-date materials. Communications professionals in states and local areas will be able to localize and download most resources, including posters, brochures, fact sheets, media kits, webcasts, and archived satellite broadcasts. Much of the material will also be available through e-mail or mail orders. Material will include color and black and white versions for healthcare and public health professionals and for public audiences, as well as specific versions for low-literacy populations. As appropriate and feasible, material will be provided in a variety of languages.

One of the most comprehensive and practical resources for communications professionals is the CDCynergy CD-ROM set produced by CDC. Emergency Risk Communication CDCynergy is applicable to communicating before and during an influenza pandemic. Communications staff also may find the CDCynergy 3.0 disk helpful. Information about CDCynergy is available on CDC's website at <http://www.cdc.gov/communication/cdcynergy.htm>.

Communicating in a Crisis: Risk Communication Guidelines for Public Officials is available on SAMHSA's website at <http://www.riskcommunication.samhsa.gov/index.htm> and bound copies can be ordered online at no charge from SAMHSA's National Mental Health Information Center (<http://store.mentalhealth.org/publications/ordering.aspx>) or by calling 1-800-789-2647. This pocket reference describes basic skills and techniques for clear, effective crisis communications and information dissemination, and provides some of the tools of the trade for media relations.

### Other resources

National Vaccine Program Office Pandemic Influenza Website  
<http://www.HHS.gov/nvpo/pandemics/>

WHO Pandemic Influenza Website  
<http://www.who.int/csr/disease/influenza/pandemic/en/>

MMWR Guide for Influenza  
[http://www.cdc.gov/mmwr/mguide\\_flu.html](http://www.cdc.gov/mmwr/mguide_flu.html)

Epidemic Information Exchange (Epi-X)  
<http://www.cdc.gov/mmwr/epix/epix.html>

Health Alert Network (HAN)  
<http://www.bt.cdc.gov/documentsapp/HAN/han.asp>; <http://www.phppo.cdc.gov/han>

Centers for Public Health Preparedness  
[www.asph.org/acphp](http://www.asph.org/acphp)

- This website provides locating information and links to the 40 centers involved in this network. The centers form a unique partnership that includes accredited schools of public health, dentistry schools, medical schools, veterinary schools, and state and local health departments. Together, the partners provide a countrywide defense system through the preparation of front-line public health workers and first responders.

Vaccine-Specific Sites and Resources

Vaccine Adverse Events Reporting System (VAERS) website at <http://vaers.hhs.gov/> or call 1-800-822-7967

#### Surveillance Sites

CDC Influenza Surveillance Data

EISS: European Influenza Surveillance Scheme

EuroGROG: International Influenza Surveillance

World Health Organization (WHO): Flunet

#### Outbreak Sites

Animal and Plant Health Inspection Service (APHIS), Veterinary Services, U.S. Department of Agriculture (USDA)

APHIS coordinates efforts to prepare for and respond to outbreaks of exotic animal diseases, including highly pathogenic avian influenza. Results of surveillance for influenza A viruses in avian species in the United States are reported each year by the National Veterinary Services Laboratories in the Proceedings of the U.S. Animal Health Association Annual Meeting.

World Health Organization Disease Outbreak Site

The World Health Organization (WHO): disease outbreaks

#### Research Sites

National Institute of Allergy and Infectious Diseases (NIAID)

<http://www.niaid.nih.gov/dmid/influenza/pandemic.htm>

USDA Agricultural Research Service

Agricultural Research Service (ARS), USDA

The ARS' Southeast Poultry Research Laboratory publishes information on avian influenza research and contacts for further information.

Manufacture and Licensing of Influenza Vaccine

Center for Biologics Evaluation and Research (CBER), FDA

CBER plays a critical role in the manufacture and licensing of influenza vaccine.

WHO Global Influenza Preparedness Plan

[http://www.who.int/csr/resources/publications/influenza/WHO\\_CDS\\_CSR\\_GIP\\_2005\\_5/en/index.html](http://www.who.int/csr/resources/publications/influenza/WHO_CDS_CSR_GIP_2005_5/en/index.html)

## APPENDIX 4. HHS PANDEMIC INFLUENZA RISK COMMUNICATION AND PUBLIC OUTREACH STRATEGY

### OVERVIEW

Pandemic influenza risk communication strategies are a critical and necessary component of pandemic influenza preparedness. To be effective, these strategies should be based on scientifically derived risk communications principles and are critical before, during, and after an influenza pandemic. Effective communication guides the public, the news media, health-care providers, and other groups in responding appropriately to outbreak situations and adhering to public health measures.

The main objective of this HHS communication strategy is to prepare the U.S. public and communities for an influenza pandemic by developing messages and materials to share with local, public and private sectors as well as our global partners. In advance of a pandemic, a system can be developed for alerting the public and draft messages and materials can be prepared.

A critical component of national preparedness for an influenza pandemic is informing the public about this potential threat and providing a solid foundation of information upon which future actions can be based. Once a pandemic occurs, our ability to communicate effectively will help HHS manage the public health implications of a pandemic. Studies have shown that the public will respond and cooperate more readily if they are involved directly in discussions and planning for future events. The HHS plan includes both strong risk communication and public outreach in order to build public trust, confidence, and cooperation. For many communities, local leaders may have to rely on risk communication as the primary tool to manage the crisis.

The communication strategy provides HHS guidance on the type of information that is crucial to convey in initial messages in order to prompt appropriate public responses after a crisis situation; the messages that can be delivered prior to, during, and after an incident; the obstacles to effective communications and how they can be minimized; opportunities that currently exist and how to maximize resources; the questions that we can anticipate from the public. This strategy reflects a two year agenda for pandemic preparedness communication and public outreach activities.

Importantly, pandemic influenza risk communication must be approached differently than many other disasters and emergencies. For example, pandemic influenza is likely to be wide-spread (not localized) and will therefore strain National resources. Communities will need to develop local plans for community continuity. In addition, pandemic influenza is likely to be a prolonged event, which will require a plan for ensuring sustained societal functions.

The objectives of this HHS communication strategy are to:

- prepare the U.S. public and communities for a pandemic;
- communicate the need for local preparedness and that Because of t "not business as usual";
- develop central messages and materials that can be shared broadly;
- coordinate across HHS and other Federal Departments; and
- provide support to our global partners.

### GENERAL RISK COMMUNICATION PRINCIPLES

Using sound and thoughtful risk communication strategies can assist public officials in preventing fear-driven, and potentially damaging public responses to crises such as bioterrorism and pandemic disease outbreaks. These strategies can help foster trust and confidence that are vital to public health.(Covello et al., 2001; Maxwell, 1999). Before a crisis occurs, public officials can prepare communities, risk managers, government spokespersons, public health officials, the news media, physicians, and hospital personnel with appropriate messages that can help build public confidence in public officials and the measures they recommend. (O'Toole, 2001).

The HHS National Pandemic Influenza Risk Communications and Public Outreach Strategy follows seven key risk communications concepts.

1. When health risks are uncertain, as likely will be the case during an influenza pandemic, people need information about what is known and unknown, and interim guidance to formulate decisions to help protect their health and the health of others.
2. An influenza pandemic will generate immediate, intense, and sustained demand for information from the public, healthcare providers, policy makers, and news media. Healthcare workers and public health staff may need training in media relations and public health communications.
3. Timely and transparent dissemination of accurate, science-based information about pandemic influenza and the progress of the response can build public trust and confidence, particularly when such communication efforts are guided by established principles of risk communication.
4. Coordination of message development and release of information among federal, state, and local health officials is critical to help avoid confusion that can undermine public trust, raise fear and anxiety, and impede response measures.
5. Guidance to community members about how to protect themselves and their family and colleagues is an essential component of crisis management.
6. Information to public audiences should be technically correct and sufficiently complete to encourage support of policies and official actions without seeming patronizing to the public.
7. Information presented during an influenza pandemic should minimize speculation and avoid over-interpretation of data, overly confident assessments of investigations and control measures, and critical comments related to other jurisdictions.

**The two most important concepts relate to communicating uncertainty, openly and honestly acknowledging that “this will not be business as usual.”**

Recognizing and admitting uncertainty is a component of most risk communication situations (Plough et al., 1988; and Chess, 1989). Scientific uncertainty can complicate communications when officials try to satisfy the public's demand for reliable and meaningful information for many risk situations. Public health officials frequently face the dilemma of having to acknowledge and explain uncertainty to a public that thinks scientific findings are precise, repeatable, and reliable. Moreover, the public often associates correlation and association as being the same as causality. As a result, officials often face the additional task of trying to explain the data's limitations and uncertainties. Audiences need to be provided as much information as possible to help them understand that uncertainty is part of the process and that the answers may change as new information and science becomes available.

**Public officials must also acknowledge that a crisis demands an acknowledgment that “this will not be business as usual.” This can be communicated by:**

- Emphasizing the rationale and importance of adherence to public health measures that some people may consider intrusive (e.g., quarantine).
- Helping to set reasonable expectations of public health and health care systems.
- Promptly address rumors, inaccuracies, and misperceptions.
- Minimizing stigmatization that may occur during a pandemic.
- Ensuring that high-risk groups and others with special needs (e.g., non-English speaking populations, difficult-to-reach communities, and persons living in institutional settings) receive appropriate information.
- Acknowledging the anxiety, distress, and grief that people experience during long-term, major public health crises such as pandemics.



## HHS PANDEMIC INFLUENZA RISK COMMUNICATION AND PUBLIC OUTREACH STRATEGY

During the prepandemic or interpandemic period, national, state, and local communities need to disseminate messages explaining why pandemic influenza is a potential public health threat, what is being done to prepare, how a pandemic would be different from annual influenza outbreaks, and what communities can do in advance. A portfolio of materials, including other sources of information is being developed by HHS for use by communities and other groups. A national website [www.pandemicflu.gov](http://www.pandemicflu.gov) will be updated regularly and serve as a national information clearinghouse. Nine key components define the HHS communications strategy:

### 1) PLANNING AND ASSESSMENT OF CURRENT KNOWLEDGE

- Determine what communications actions will be taken and by whom in advance of a pandemic (i.e. prepandemic) and once a pandemic is confirmed by WHO
- Ascertain communication needs for various audience segments (i.e. What materials, resources, processes, and systems, will be necessary in both phases?)
- Conduct an environmental scan or an assessment of current knowledge of pandemic influenza, which will include:
- Scholarly literature review on Avian Flu or whatever pandemic flu strain is the problem, public health risks, public and political response to similar incidents (e.g., SARS),.
- Review of media coverage of pandemics, Review of web sources
- Assess and analyze media and public baseline knowledge and attitudes.
- Review current national and international efforts and programs to control the pandemic and work with international partners to coordinate activities (WHO)

### 2) FORMATIVE AUDIENCE RESEARCH

- Define public perceptions, attitudes, beliefs, . Study these from communication perspective to determine how to position information so that people attend to messages and act upon them.
- Conduct 2 sets of 9 cognitive interviews and 16 focus groups with general public.
- Conduct 18 telephone stakeholder interviews with health professionals and community leaders.

### 3) MESSAGE AND MATERIAL DEVELOPMENT

- Develop prepandemic (WHO intrapandemic and pandemic alert levels) and pandemic messages and materials based on risk communication principles, as outlined in the WHO Outbreak Communication Guidelines.
- Define audiences and develop materials for these audiences.
- Develop message maps and concepts appropriate for each "Phase" of an influenza pandemic development. To test event messages, a video-based scenario will be used to simulate emotional response during a pandemic.
- Coordinate with other agencies to identify pre-event and event material needs and to develop new materials as needed. Materials may include:
  - "HHS Prepares for Pandemic Influenza" – a sixteen page, color version of the pandemic plan for the public that describes the major issues, decisions, actions regarding pandemic influenza.
  - Live announcer copy
  - Core Q&As
  - Hotline response materials

- Fact sheets
- B-roll
- Graphics to support HHS communication (animation)
- Conduct focus groups with general public to pretest event messages separately and/or materials. Provide additional support for material development as needed.

#### **4) CROSS GOVERNMENT COLLABORATION AND COORDINATION**

- Establish a cross agency working group that includes communication, policy and subject matter experts. This working group will review and shares strategies and activities being undertaken by each agency and develop a coordinated communication approach. This working group will:
  - Develop consistent messages about pandemic influenza
  - Ensure common understanding of HHS objectives and strategies
  - Leverage existing activities and resources to address pandemic influenza
  - Develop an inventory of current activities
  - Identify gaps and make recommendations on how they can be filled
  - Coordinate media planning, stakeholder outreach
  - Coordinate communications systems as appropriate.
  - Outreach to other Departments in the Federal government and international partners.

#### **5) TRAINING**

- Coordinate Training sessions for emergency risk communication among "master trainers" as identified through previous training courses provided by CDC, as well as CDC recommendations. These core trainers would then provide on the ground training within their regions and states focusing specifically on Pandemic Influenza.
- Conduct media training for spokespersons on public health crisis response and risk communications principles.
- Prepare a highly specialized risk communication and message development workshop. This workshop would be focused on building trust across policy makers, communications experts, and subject matter experts across HHS and partner agencies to support effective risk communication during an outbreak of Pandemic Influenza.
- Run a senior official pandemic influenza/communication-focused exercise in cooperation with other government departments.

#### **6) MEDIA OUTREACH**

- Coordinate closely with the CDC and other HHS agencies on a National Pandemic Influenza Media Plan , which would include:
- Develop core press materials to serve as backgrounder documents for federal, state and local partners, using existing CDC materials as a starting point
- Conduct media briefing with key national outlets to demonstrate how HHS will function and discuss community planning
- Coordinate media relations with Canada, UK, Mexico, WHO, PAHO, Japan, the EU, and GHSAG, as appropriate.
- Coordinate and host a total of six informational roundtables with:

Key science and health writers/reporters to lay out the groundwork for basic understanding of a pandemic, the risk of an outbreak, the public health response, fact/myths about pandemics, the role of infection control in managing the outbreak, etc.

Key minority media and those representing special-needs groups.

- Review and enhance media lists.

## 7) COMMUNITY CONTINUITY PLANNING

In collaboration with other government offices (e.g. Department of Education) HHS will develop toolkits specific to different audience segments (e.g. socio-economic considerations) to help inform them about the potential threat of a pandemic, the implications of a pandemic for this sector, and what this sector needs to know in advance so that they can best prepare.

HHS will:

Conduct research into existing infrastructures and plans that can be models for this effort.

Engage community leaders in pre-pandemic planning

- Convene multiple stakeholders meeting.
- Publish proceedings as a document on community continuity planning for Pandemic Influenza and distribute widely including online/electronically
- Develop tool kits for communities for continuity planning working with other governmental partners (e.g. Dept of Education on Tool Kit for Schools)
- Provide exercises/scenarios with leaders' guide on the Pandemic so that communities can use these to determine what they need to put in place, what choices/options they face.
- Develop an online exercise activity designed to help community groups plan for ensuring that community members have access to needed services (e.g., child care, transportation to essential appointments and essential supplies) in a pandemic influenza event. The exercise will be designed similarly to a board game. The outcome for community groups participating in the game will be to have developed a set of materials such as telephone trees, transportation plans, and community maps marked with the location of essential services, the location of individuals who need assistance, etc. Training will be based on core scenario developed for other trainings.

## 8) BUSINESS CONTINUITY PLANNING

**Stimulate and support business leader continuity planning.**

Engage Business Leaders in Pandemic Flu Continuity Planning.

Help them understand nature of the outbreak and why employees should stay home. Provide information on how to plan to continue operations during a pandemic.

Support their exploration of how they can use volunteers to deliver good and services to quarantined community members.

Support their exploration of how they can support public health response

**Conduct Business Roundtables**

Work with SBA, DOC, DOL and other stakeholders such as Chambers of Commerce, to convene four key business leader and union representatives in a series of roundtables segmented by business size, and/or geography, and/or nature of business.

- Publish outcome of meeting proceedings and widely distribute

- Provide handbook for business leaders and other stakeholders to encourage and support their planning for/coping with Pandemic Influenza. This would include background information on all relevant topics.

## 9) PUBLIC ENGAGEMENT

### Expert Discussions

Host roundtable discussions with medical influencers and opinion leaders Identify and convene key health professional influencers for an "expert discussion" to better understand the likely criticisms the agency may face from the public, and also help these influencers better understand the challenges of pandemic influenza management, relevant research underway, etc. so that they will have a better understanding of what they are commenting on if called upon by the media during an outbreak.

**Town Hall Meetings in Six Cities** (San Diego, San Francisco or Seattle; Detroit; Miami; Dallas or Fort Worth; Philadelphia and Mobile) Work with Council for Excellence in Government to convene town meetings across the nation with key stakeholders to engage them in planning for pandemic and community continuity.

- public health/public officials
- private sector clinicians
- education sector
- business sector
- non-profit/volunteer sector

Format of town meetings will include a primary session of 200 participants across stakeholder groups, with breakout sessions following. This will include location scouting, panelist research, media and community outreach. Tasks will include:

- secure panelists and sub panelists in the following areas: HHS leadership; local public health leadership; local private sector clinical officials; local nonprofit/volunteer community; local education community; local business leaders
- publicize event through media partnerships and strategic outreach to build community audience of 200 people
- conduct on-line registration that includes audience pre-event polling
- research on locality and specific issues and concerns for discussion
- secure nationally recognized media personality for moderator and A/V vendor
- produce moderator guide (show script)
- oversee all media relations prior, during and post event
- produce town hall event, including show production, live audience polling and on-site event management
- produce and facilitate post town hall leadership symposium

**Public Dialogue Sessions**—Meetings with National stakeholder organizations at IOM in July, Sept to discuss priority groups for vaccination during a pandemic. Meetings with local citizens in Atlanta, Omaha, Boston, and Portland in August and September.

## 10) INTERNATIONAL SUPPORT

- Work with WHO to support public health risk communications needs globally.
- If requested, provide template materials that can be adapted to local needs.
- Support global risk communication training through WHO

## HHS RESPONSIBILITIES

### Pandemic Period

Develop key messages and materials and conduct audience research and message testing and share results with state and local communications staff.

Provide tools and resources through the [www.pandemicflu.gov](http://www.pandemicflu.gov) and other avenues to help educate state and local communications staff.

Identify and train lead spokespersons.

Provide state and local health agencies with guidance about developing communications aspects of preparedness plans.

Work with state and local governments to incorporate communications preparedness as part of larger preparedness exercises.

Work with other non-public health sectors to help provide communications tools for their communities.

Work with the World Health Organization (WHO) and other international public health partners to plan and coordinate communication activities for an influenza pandemic.

### Pandemic Alert

Coordinate pandemic influenza media messages to ensure consistency

Provide regular updates about situations that pose potential pandemic influenza threats (e.g., through Health Alert Network [HAN] notices and Web site postings).

Distribute educational messages about pandemic influenza and ways that people can protect themselves and their families

Distribute practical information, such as travel advisories, infection control, availability and use of antiviral medications and vaccines, and specific public health actions that may be needed.

Address rumors and false reports regarding pandemic influenza threats.

### Pandemic Period

Coordinate pandemic influenza media messages to ensure consistency

Coordinate communications activities with state and local communications staff, including regional or local communications centers as appropriate.

Promptly respond to rumors and inaccurate information to minimize concern, social disruption, and stigmatization





# **supplement 11** **workforce support: psychosocial considerations and information needs** **TABLE OF CONTENTS**

|                                                                                       |        |
|---------------------------------------------------------------------------------------|--------|
| SUMMARY OF PUBLIC HEALTH ROLES AND RESPONSIBILITIES IN WORKFORCE SUPPORT .....        | S11-2  |
| S11-I. RATIONALE .....                                                                | S11-3  |
| S11-II. OVERVIEW .....                                                                | S11-3  |
| S11-III. RECOMMENDATIONS FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS ..          | S11-3  |
| A. Institutionalizing psychosocial support services.....                              | S11-3  |
| B. Preparing workforce support materials .....                                        | S11-4  |
| C. Developing workforce resilience programs.....                                      | S11-5  |
| S11-IV.RECOMMENDATIONS FOR THE PANDEMIC PERIOD .....                                  | S11-5  |
| A. Delivering psychosocial support services .....                                     | S11-5  |
| B. Providing information to responders.....                                           | S11-6  |
| 1. Healthcare providers .....                                                         | S11-6  |
| 2. Other occupational groups .....                                                    | S11-6  |
| 3. Stigmatization issues.....                                                         | S11-6  |
| C. Implementing workforce resilience programs.....                                    | S11-6  |
| 1. Predeployment/assignment.....                                                      | S11-7  |
| 2. During deployment/assignment .....                                                 | S11-7  |
| 3. Post-deployment/assignment .....                                                   | S11-7  |
| Box 1. Psychosocial Issues for Response Workers .....                                 | S11-8  |
| Box 2. Psychosocial Issues for Families of Response Workers .....                     | S11-8  |
| Box 3. Impact of Pandemic Influenza on Healthcare Workers.....                        | S11-9  |
| Box 4. Lessons Learned from the 2004-2005 Tsunami Relief Effort.....                  | S11-9  |
| Appendix 1. Bibliography: Psychosocial Issues Related to Public Health Emergencies .. | S11-10 |
| Appendix 2. Checklist for Workforce Support Services/Resources.....                   | S11-12 |
| Appendix 3. Psychological First Aid for Emergency Responders .....                    | S11-14 |



## **SUMMARY OF PUBLIC HEALTH ROLES AND RESPONSIBILITIES IN WORKFORCE SUPPORT**

### **INTERPANDEMIC AND PANDEMIC ALERT PERIODS**

#### **Healthcare institutions, state and local health agencies, first-responder organizations, and employers of essential service workers:**

- Institutionalize psychosocial support services for employees who participate in or provide support for the response to public health emergencies such as influenza pandemics.
- Prepare educational and training materials on psychosocial issues for distribution to employees during an influenza pandemic.

#### **State and local health departments and other groups:**

- Lay the groundwork for the development and implementation of workforce resilience programs to maximize responders' performance and personal resilience during a public health emergency.
- Use behavioral health expertise to develop public health messages, train staff on the use of personal protective equipment (PPE), and conduct other relevant activities.

#### **HHS agencies:**

- Create, collect, and provide educational and training materials on psychosocial issues related to pandemic influenza for use by hospital administrators, emergency department staff, safety and security professionals, behavioral health providers, social workers, psychologists, chaplains, and others.
- Provide guidance on the development of self-care strategies and workforce resilience programs.

### **PANDEMIC PERIOD**

#### **Healthcare institutions, state and local health agencies, first-responder organizations, and employers of essential service workers:**

- Provide psychological and social support services for employees and their families.
- Address stigmatization issues that might be associated with participation in such services.

#### **Healthcare institutions:**

Provide employees with ongoing access to up-to-date information on healthcare and training issues, as well as on the national and local status of the pandemic.

#### **State and local health departments and other groups:**

- Implement workforce resilience programs.

#### **HHS agencies:**

- Provide medical, public health, and community partners with educational and training materials on psychosocial issues related to pandemic influenza.
- Provide occupational health guidance on psychosocial issues related to the pandemic, including information on anticipated reactions to restrictive public health measures such as quarantine.

## S11-I. RATIONALE

The response to an influenza pandemic will pose substantial physical, personal, social, and emotional challenges to healthcare providers, public health officials, and other emergency responders and essential service workers (Box 1). Experience with disaster relief efforts suggests that enhanced workforce support activities can help responders remain effective during emergencies (Appendix 1).

During an influenza pandemic, however, the occupational stresses experienced by healthcare providers and other responders are likely to differ from those faced by relief workers in the aftermath of a natural disaster. Globally and nationally, a pandemic might last for more than a year, while disease outbreaks in local communities may last 5 to 10 weeks. Medical and public health responders and their families will be at personal risk for as long as the pandemic continues in their community. Special planning is therefore needed to ensure that hospitals, public health agencies, first-responder organizations, and employers of essential service workers are prepared to help employees maximize personal resilience and professional performance. An essential part of this planning effort involves the creation of alliances with community-based organizations and nongovernmental organizations with expertise in and resources for psychosocial support services or training.

## S11-II. OVERVIEW

Recommendations for the Interpandemic and Pandemic Alert Periods focus on the establishment of psychosocial support services that will help workers manage emotional stress during the response to an influenza pandemic and resolve related personal, professional, and family issues. The recommendations also address the preparation of informational materials for employees and their families and the development of workforce resilience programs to assist families of deployed workers. Recommendations for the Pandemic Period focus on the delivery of psychosocial support services to response workers, provision of occupational health information to healthcare providers, and implementation of workforce resilience programs.

**Supplement 11** addresses the psychological and social ("psychosocial") needs of the occupational groups that will participate in the response to an influenza pandemic. These groups include:

- Healthcare workers who provide medical care to ill persons
- Emergency field workers and other public health personnel who help control the spread of infection
- First-responder and nongovernmental organizations whose employees assist affected groups (e.g., persons in quarantine or isolation)
- Essential service workers whose activities maintain normal functions in the community and minimize social disruption
- Family members of all of these groups

Examples of the psychosocial issues faced by these groups and their families are listed in Boxes 1 and 2. Preparedness planning to address these issues will also be useful in responding to other types of public health emergencies. A checklist outlining key workforce support and resource concerns is provided to assist planners (see Appendix 2).

## S11-III. RECOMMENDATIONS FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS

### A. Institutionalizing psychosocial support services

Healthcare institutions and state and local health agencies should consider incorporating psychosocial support services into occupational health and emergency preparedness planning for an influenza pandemic. First responders and essential service workers employed by companies and local governments (Box 2) might also benefit from these services. Healthcare and public health planners should also contact community-based organizations and nongovernmental organizations to determine the types of psychological and social support services and training courses available in their jurisdictions.

- Healthcare and public health officials should consider needs for information sharing with emergency planners in schools, law enforcement agencies, and local businesses.
- Planning for the provision of psychosocial support services might include the following activities:
- Ensuring that administrators, managers, and supervisors are familiar with and actively encourage the use of tools and techniques for supporting staff and their families during times of crisis (see S11-IV.A and Appendix 3)
- Training staff in hospitals and occupational health clinics (e.g., social workers, psychiatrists, nurses, psychologists, counselors) in behavioral techniques to help employees cope with grief, stress, exhaustion, anger, and fear during an emergency (see S11-IV.A and Appendix 3)
- If feasible, providing training in psychological support services to persons who are not behavioral health professionals (e.g., primary-care clinicians, emergency department staff, medical/surgical staff, safety and security personnel, behavioral health staff, chaplains, community leaders, staff of cultural and faith-based organizations)
- Identifying additional resources that can be available to employees and their families during and after a pandemic
- Developing strategies to assist staff who have child-care or elder-care responsibilities or other special needs that might affect their ability to work during a pandemic

## B. Preparing workforce support materials

Employers of response workers and providers of essential services should obtain or prepare workforce support materials (in hard copy or electronic format) for distribution during a pandemic. These materials should be designed to do the following:

- Educate and inform employees about emotional responses they might experience or observe in their colleagues and families (including children) during an influenza pandemic and about techniques for coping with these emotions (see Appendix 3).
- Educate employees about the importance of developing "family communication plans" so that family members can maintain contact during an emergency.
- Describe workforce support services that will be available during an emergency, including confidential behavioral health services and employee assistance programs.
- Answer questions about infection control practices to prevent the spread of pandemic influenza in the workplace (see **Supplement 4**) and employment issues related to illness, sick pay, staff rotation, and family concerns.

Healthcare institutions should be prepared to provide materials that address healthcare and training issues related to pandemic influenza (see S11-IV.B). To support these efforts, CDC, HRSA, NIH, and SAMHSA will collaborate with the Department of Homeland Security, other federal agencies, and nongovernmental organizations to identify or develop educational materials on:

- Stressors related to pandemic influenza
- Signs of distress
- Traumatic grief
- Psychosocial aspects related to management of mass fatalities
- Stress management and coping strategies
- Strategies for building and sustaining personal resilience
- Behavioral and psychological support resources
- Strategies for helping children and families in times of crisis
- Strategies for working with highly agitated patients

## C. Developing workforce resilience programs

State and local health agencies should consider establishing workforce resilience programs that will help deployed workers prepare for, cope with, and recover from the social and psychological challenges of emergency field work. CDC has used this approach with staff members who participated in the tsunami relief effort in 2004–2005 and the Marburg hemorrhagic fever outbreak in Angola in 2005.

To prepare for implementation of workforce resilience programs to cope with the special challenges posed by an influenza pandemic, agencies should do the following:

- Plan for a long response (i.e., more than 1 year).
- Identify pre-deployment briefing materials.
- Augment employee assistance programs with social support services for the families of deployed workers (see S11–IV.C).
- Provide program administrators and counselors with information on:
  - Cognitive, physiological, behavioral, and emotional symptoms that might be exhibited by patients and their families (especially children), including symptoms that might indicate severe mental disturbance
  - Self-care in the field (i.e., actions to safeguard physical and emotional health and maintain a sense of control and self-efficacy)
  - Cultural (e.g., professional, educational, geographic, ethnic) differences that can affect communication
  - Potential impact of a pandemic on special populations (e.g., children, ethnic or cultural groups, the elderly).

## S11–IV. RECOMMENDATIONS FOR THE PANDEMIC PERIOD

### A. Delivering psychosocial support services

Healthcare facilities and public health agencies—as well as companies and local governments that employ essential service providers—should make full use of public health techniques and communication tools that can help response workers manage emotional stress and family issues and build coping skills and resilience. These tools can include:

- Stress control/resilience teams. These teams can assist and support employees and foster cohesion and morale by:
  - Monitoring employee health and well-being (in collaboration with occupational health clinics, if possible)
  - Staffing “rest and recuperation sites” (see below)
  - Distributing informational materials (see S11–III.B).

Stress control teams in hospitals should observe recommended infection control precautions.

- Rest and recuperation sites. Sites can be stocked with healthy snacks and relaxation materials (e.g., music, relaxation tapes, movies), as well as pamphlets or notices about workforce support services.
- Confidential telephone support lines staffed by behavioral health professionals
- Services for families. Services to families of employees who work in the field, work long hours, and/or remain in hospitals or other workplaces overnight might include:
  - Help with elder care and child care
  - Help with other issues related to the care or well-being of children
  - Provision of cell phone or wireless communication devices to allow regular communication among family members (see S11–III.B)
  - Provision of information via websites or hotlines
  - Access to expert advice and answers to questions about disease control measures and self care.

- Information for commuters. Workers might need alternative transportation and scheduling (e.g., carpooling, employer-provided private transportation, alternate work schedules during off-peak hours) to avoid exposure to large groups of potentially infected persons.
- Services provided by community- and faith-based organizations. Activities of these organizations can provide relaxation and comfort during trying and stressful times.

A list of additional resources is provided in Appendix 3.

## **B. Providing information to responders**

### **1. Healthcare providers**

Healthcare providers—especially those who work in hospitals—are likely to be under extreme stress during a pandemic (see Box 3) and will have special needs for open lines of communication with employers and access to up-to-date information. Healthcare facilities should ensure that employees have ongoing access to information on the following:

- International, national, and local progress of the pandemic
- Work issues related to illness, sick pay, staff rotation, shift coverage, overtime pay, use of benefit time, transportation, and use of cellphones
- Family issues, especially availability of child care
- Healthcare issues such as availability of vaccines, antiviral drugs, and personal protective equipment (PPE); actions to address understaffing or depletion of PPE and medical supplies; infection control practices as conditions change; approaches to ensure patients' adherence to medical and public health measures without causing undue anxiety or alarm; management of agitated or desperate persons; guidance on distinguishing between psychiatric disorders and common reactions to stress and trauma; management of those who fear they may be infected, but are not (so-called "worried well"); and guidance and psychosocial support for persons exposed to large numbers of influenza cases and deaths and to persons with unusual or disturbing disease symptoms.
- Because healthcare workers might be called upon to fill in for sick colleagues and perform unfamiliar tasks, healthcare facilities should consider providing written instructions for "just-in-time" cross training on essential tasks.

### **2. Other occupational groups**

Other occupational groups that might participate in the response to pandemic influenza (including police, firefighters, and community outreach workers) should receive training materials that will help them anticipate behavioral reactions to public health measures such as movement restrictions (e.g., quarantine, isolation, closure of national or regional borders), especially if such actions are compounded by an economic crisis or abrupt loss of essential supplies and services.

### **3. Stigmatization issues**

Healthcare workers and other emergency responders should be provided with information on what to do if they or their children or other family members experience stigmatization or discrimination because of their role in the pandemic influenza response. Hospital public affairs offices should be prepared to address these issues without delay.

## **C. Implementing workforce resilience programs**

During an influenza pandemic, state and local health agencies should consider implementing workforce resilience programs that meet the special needs of deployed workers—including workers who do not change job site but whose assignments shift to respond to the pandemic—and the central operations personnel who support them around the clock. First-responder or nongovernmental organizations that send employees or volunteers to assist patients at home or in hospitals might establish similar programs. Workforce resilience programs could provide the following services:

## 1. Predeployment/assignment

- Conduct briefings and training on behavioral health, resilience, stress management issues, and coping skills.
- Train supervisors in strategies for maintaining a supportive work environment.

## 2. During deployment/assignment

- To support responders in the field:
  - Deploy several persons as a team and/or assign "buddies" to maintain frequent contact and provide mutual help in coping with daily stresses.
  - Frequently monitor the occupational safety, health, and psychological well-being of deployed staff.
  - Provide access to activities that help reduce stress (e.g., rest, hot showers, nutritious snacks, light exercise).
  - Provide behavioral health services, as requested.
- For central operations personnel:
  - Enlist stress control or resilience teams to monitor employees' occupational safety, health, and psychological well-being (see S11-IV.A).
  - Establish rest and recuperation sites (see S11-IVA), and encourage their use.
  - Provide behavioral health services, as requested.
- For families of responders:
  - Provide all of the services listed under "Services for Families" in S11-III.A (Note: Services for Families not listed in S11-III.A)
  - Enlist employee assistance programs to provide family members with instrumental support (e.g., assistance obtaining food and medicine) and psychosocial support (e.g., family support groups, bereavement counseling, and courses on resilience, coping skills, and stress management).
  - Provide a suggestion box for input via e-mail or anonymous voice-mail with a toll-free number.
  - Continue to provide outreach to employees' families to address ongoing psychological and social issues.

Throughout the response, policies on personnel health and safety should be reviewed and revised, as needed.

## 3. Post-deployment/assignment

- Interview responders and family members (including children) to assess lessons learned that might be applied to future emergency response efforts (see Box 4).
- Provide ongoing access to post-emergency psychosocial support services for responders and their families (on-site or through partner organizations).
- Conduct an ongoing evaluation of the after-effects of the pandemic on employees' health, morale, and productivity.

## BOX 1. PSYCHOSOCIAL ISSUES FOR RESPONSE WORKERS

Psychosocial issues that response workers might need to address include:

- Illness and death among colleagues and family members
- Fear of contagion and/or of transmitting disease to others
- Shock, numbness, confusion, or disbelief; extreme sadness, grief, anger, or guilt; exhaustion; frustration
- Sense of ineffectiveness and powerlessness
- Difficulty maintaining self-care activities (e.g., getting sufficient rest)
- Prolonged separation from family
- Concern about children and other family members
- Constant stress and pressure to keep performing
- Domestic pressures caused by school closures, disruptions in day care, or family illness
- Stress of working with sick or agitated persons and their families and/or with communities under quarantine restrictions
- Concern about receiving vaccines and/or antiviral drugs before other persons

These issues may be exacerbated by:

- Lack of information
- Rumors, misconceptions, or conspiracy theories
- Loss of faith in health institutions, employers, or government leaders
- Belief that medical resources are not available or fairly distributed
- Death of immediate supervisors or other leaders in the response effort
- Mass casualties and deaths among children
- Economic collapse or acute shortages of food, water, electricity, or other essential services
- Restrictions on civil liberties that are perceived to be inequitable
- Infection control procedures that limit personal contact or hinder communications

Psychosocial issues related to the general public are addressed in **Supplement 10**.

## BOX 2. PSYCHOSOCIAL ISSUES FOR FAMILIES OF RESPONSE WORKERS

The families of responders will face many challenges in addition to the fears and disruptions that everyone will face during a pandemic. For example:

- Responders might be frustrated, tired, worried, irritable, argumentative, restless, emotional, or distressed.
- Responders might be impatient and less understanding, energetic, optimistic, good natured, or helpful than usual.
- Increased emergency work loads (which might be exacerbated by staffing shortages) can make it difficult for responders to communicate regularly with family members.
- Family members might experience stigmatization or discrimination.



### **BOX 3. IMPACT OF PANDEMIC INFLUENZA ON HEALTHCARE WORKERS**

In addition to the issues faced by all response workers (Box 1), healthcare workers may experience:

- Increased risk of exposure to pandemic influenza
- Constant need to take special precautions to avoid exposure to the pandemic virus
- Illness and death among patients, as well as among colleagues and family members
- Stigmatization and discrimination associated with being perceived as a source of contagion
- Ethical dilemmas, such as conflicts between one's roles as healthcare provider and parent/spouse, or concern about receiving vaccines or antiviral drugs before other people
- Increased difficulty in performing crucial tasks and functions as the number of severely ill patients increases, the healthcare staff decreases, and medical and infection control resources are depleted
- Frustration regarding the need/expectation to maintain business as usual
- Physical isolation associated with use of infection control measures that limit interpersonal contact

Psychosocial issues related to hospital workers are also addressed in **Supplement 3**.

### **BOX 4. LESSONS LEARNED DURING THE 2004-2005 TSUNAMI RELIEF EFFORT**

- It is difficult to prepare responders for everything they might encounter.
- Even seasoned responders can face situations and issues that cause uneasiness and distress.
- It is not unusual for responders to be asked to work outside their areas of expertise.
- Concerns about family and friends rank high on responders' lists of priorities.
- Timely, accurate, and candid information should be shared to facilitate decision-making.
- Self-help activities are essential to mission completion.
- Everything possible should be done to safeguard responders' physical and emotional health.
- Responders do not need to face response challenges alone. They may share their experiences with buddies, teammates, family members, and colleagues.
- It is especially difficult for responders to maintain personal resilience when they witness the deaths of children.
- Organizational differences among groups of responders and cultural differences between victims and responders can impede the timely and efficient provision of emergency services.

## APPENDIX 1. BIBLIOGRAPHY: PSYCHOSOCIAL ISSUES RELATED TO PUBLIC HEALTH EMERGENCIES

American College of Emergency Physicians (ACEP). News release: Disaster medicine experts highlight strategies for managing hospital patient surges following a terrorism event: Massachusetts' plan for addressing patient surge capacity shared. *Annals of Emergency Medicine*. 2004 July 20.

Compton MT, Gard B, Kaslow NJ, Kotwicki RJ, Reissman DB, Schor L, Wetterhall S. Incorporating mental health into local bioterrorism response planning: experiences from the Dekalb County Board of Health. *Public Health Reports*, in press.

Fischhoff B, Gonzalez RM, Small DA, Lerner JS. Evaluating the success of terror risk communication. *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* 2003; 1(4):255-8.

Hawryluck L, Gold WL, Robinson S, Pogorski S, Galea S, and Styra R. SARS control and psychological effects of quarantine, Toronto, Canada. *Emerg Infect Dis* [serial on the Internet] 2004 Jul [2005 Feb 12]; 10(7): [about 3 p.]. Available from: <http://www.cdc.gov/ncidod/EID/vol10no7/03-0703.htm>

Knobler SL, Mack A, Mahmoud A, Lemon SM, eds. *The threat of pandemic influenza: are we ready? workshop summary*. Washington: National Academy Press, 2004. <http://www.nap.edu/books/0309095042/html/>.

Lazarus RS, Folkman S. *Stress appraisal and coping*. New York: Springer, 1984.

Maunder R, Hunter J, Vincent L, Bennett J, Peladeau N, Leszcz M, Sadavoy J, Verhaeghe LM, Steinburg R, Mazzulli T. The immediate psychological and occupational impact of the 2003 SARS outbreak in a teaching hospital. *Canadian Medical Association Journal* 2003;168(10):1245-51.

Pfefferbaum B, Reissman D, Gurwitch R, Steinberg A, Montgomery J. Community resilience mini-summit: developing community resilience for children and families March 24-25, 2004—executive summary. Los Angeles: National Child Traumatic Stress Network, 2004.

Reissman DB, Klomp RW, Kent AT, Pfefferbaum B. Exploring psychological resilience in the face of terrorism. *Psychiatric Annals* 2004; 33(8):627-32.

Reissman DB, Spencer S, Tanielian T, Stein BD. Integrating behavioral aspects into community preparedness and response systems. In: Danieli Y, Brom D & Sills J, eds. *The trauma of terrorism: sharing knowledge and shared care. An international handbook*. New York: Haworth Maltreatment and Trauma Press, 2005. (published simultaneously as the *Journal of Aggression, Maltreatment and Trauma* 2005;9(½ & ¾).

Rutter M. Psychosocial resilience and protective mechanisms. In: Rolf J, Masten AS, Cicchetti D, Nuechterlein KH, Weintraub S, eds. *Risk and protective factors in the development of psychopathology*. New York: Cambridge University Press, 1990. pp 181-214.

Sandman PM & Lanard J. Pandemic influenza risk communication: the teachable moment [monograph on the Internet]. 2004 [cited 2005 March 1]. Available from: <http://www.psandman.com/col/pandemic.htm>.

Stein BD, Tanielian TL, Eisenma DP, Keyser DJ, Burnam MA, Pincus HA. Emotional and behavioral consequences of bioterrorism: planning a public health response. *Milbank Quarterly* 2004; 82(3):413-55.

United States General Accounting Office. Hospital emergency departments: crowded conditions vary among hospitals and communities - Highlights of GAO-03-460, a report to the Ranking Minority Member, Committee on Finance, U.S. Senate [report on the linternet]. Washington: U.S. General Accounting Office; 2003 [cited 2005 Feb 2]. Available from: <http://www.gao.gov/new.items/d03460.pdf>.

Ursano, RJ, Norwood, AE, Fullerton CS. Bioterrorism: psychological and public health interventions. Cambridge: Cambridge University Press, 2004.

---

Background papers from an International Conference on Stigma and Global Health: Developing a Research Agenda (2001September 5-7; Bethesda, Maryland) are available at <http://www.stigmaconference.nih.gov/papers.html>.

## APPENDIX 2. CHECKLIST FOR WORKFORCE SUPPORT SERVICES/RESOURCES

### A. Checklist for Interpandemic and Pandemic Alert Periods

#### Include psychosocial issues in planning

- ☐ Incorporate psychosocial support services into emergency preparedness planning for an influenza pandemic.
- ☐ Coordinate with business, corporations and other private sector interests in planning for behavioral health response and consequences.
- ☐ Develop plans to prepare and support emergency service responders (e.g., police, fire, hospital emergency department staff, mortuary workers) during and following deployment.
- ☐ Prepare for a significant surge of individuals who fear they may be infected, but aren't, who may present at emergency departments or other healthcare locations, or contact health information hotlines.
- ☐ Develop a demographic picture of the community (e.g., ethnic, racial, and religious groups; most vulnerable; special needs; language minorities) and plan for how they might be reached in a disaster.
- ☐ Identify rest and recuperation sites for responders. These sites can be stocked with healthy snacks and relaxation materials (e.g., music, relaxation tapes, movies), as well as pamphlets or notices about workforce support services.
- ☐ Develop confidential telephone support lines to be staffed by behavioral health professionals.
- ☐ Use behavioral health expertise to develop public health messages, train staff on the psychological impact of the use of personal protective equipment (PPE), and conduct other relevant activities.

#### Identify and access existing resources

- ☐ Work with community-based organizations and nongovernmental organizations to determine the types of psychological and social support services and training courses available in their jurisdictions.
- ☐ Establish public-sector links with private mental health resources such as Red Cross and other national voluntary organizations active in disasters.
- ☐ Develop a plan to manage offers of assistance and invited/uninvited volunteers.
- ☐ Identify gaps, such as culturally competent and multilingual providers, that might affect disaster services.

#### Train behavioral health and related professionals in disaster response strategies

- ☐ Train behavioral health staff in hospitals, clinics, and related agencies in techniques to help people cope with grief, stress, exhaustion, anger, and fear during an emergency.
- ☐ Train nonbehavioral health professionals (e.g., primary-care clinicians, safety and security personnel, community leaders, and staff of cultural- and faith-based organizations) in basic psychological support services.
- ☐ Establish links to health and medical entities for purposes of assisting in screening potential victims for mental disorders and psychogenic symptomatology, functional impairment, substance abuse, etc.

#### Develop resources and materials

- ☐ Prepare educational and training materials on psychosocial issues for distribution to workers during an influenza pandemic.

## B. Checklist for Pandemic Period

### During the first 4 weeks

- ☐ Meet basic needs such as food, shelter, and clothing.
- ☐ Provide basic psychological support (psychological first aid).
- ☐ Provide needs assessments.
- ☐ Monitor the recovery environment (conducting surveillance).
- ☐ Provide outreach and information dissemination.
- ☐ Provide technical assistance, consultation, and training.
- ☐ Foster resilience, coping, and recovery.
- ☐ Provide triage.
- ☐ Provide treatment.
- ☐ Provide psychological and social support services for employees and their families.
- ☐ Address stigmatization issues that might be associated with participation in such services.
- ☐ Implement workforce resilience programs.
- ☐ Work with communications experts to shape messages that reduce the psychological impact of the pandemic.
- ☐ Provide medical, public health, and community partners with educational and training materials.

### During subsequent weeks

- ☐ Provide continued outreach, triage, and services.
- ☐ Monitor workforce for signs of chronic or severe psychological distress.
- ☐ Provide assistance in reintegration for workers who were deployed or isolated from work and family.

## APPENDIX 3. PSYCHOLOGICAL FIRST AID FOR EMERGENCY RESPONDERS

Along with increased efforts to institutionalize workforce services that support the emotional well-being of responders—both during and after an emergency—a consensus is growing on the usefulness of a set of psychosocial tools and techniques for providing “psychological first aid.” The organizations listed below provide information for those interested in learning more about this topic.

- American Psychiatric Association  
[www.psych.org/disasterpsych/links/weblinks.cfm](http://www.psych.org/disasterpsych/links/weblinks.cfm)
- American Psychological Association (APA) Help Center  
[www.apahelpcenter.org](http://www.apahelpcenter.org)
- Disaster Epidemiology Emergency Preparedness (DEEP) Center, University of Miami Miller School of Medicine  
[www.deep.med.miami.edu](http://www.deep.med.miami.edu)
- National Center for PTSD, Department of Veterans' Affairs  
[www.ncptsd.va.gov/](http://www.ncptsd.va.gov/)
- National Child Traumatic Stress Network  
[www.nctsnet.org](http://www.nctsnet.org)
- Project Liberty  
[www.projectliberty.state.ny.us/](http://www.projectliberty.state.ny.us/)

Resources from HHS agencies include:

- CDC/American Red Cross. Maintaining a healthy state of mind  
[http://www.redcross.org/preparedness/cdc\\_english/health.asp](http://www.redcross.org/preparedness/cdc_english/health.asp)
- National Institute of Mental Health (NIMH/NIH/HHS)  
Mental Health and Mass Violence: Evidence-Based Early Psychological Intervention for Victims/Survivors of Mass Violence: A Workshop to Reach Consensus on Best Practices. NIH Publication No. 02-5138, Washington, D.C., U.S. Government Printing Office. 2002
- Substance Abuse and Mental Health Services Administration (SAMSHA/HHS)  
Disaster Readiness and Response  
[www.samhsa.gov/Matrix/matrix\\_disaster.aspx](http://www.samhsa.gov/Matrix/matrix_disaster.aspx)  
  
Disaster Technical Assistance Center. Research listings and fact sheets on self-care  
[www.mentalhealth.samhsa.gov/dtac/Selfcare.asp](http://www.mentalhealth.samhsa.gov/dtac/Selfcare.asp)  
  
Center for Mental Health Services  
*Mental Health Response to Mass Violence and Terrorism: A Training Manual*. HHS Pub. No. SMA 3959. Rockville (MD); 2004  
*Guide to Managing Stress in Crisis Response Professions* (under development).







# Exhibit M



## CRS Report for Congress

# Pandemic Influenza: Appropriations for Public Health Preparedness and Response

Sarah A. Lister  
Specialist in Public Health and Epidemiology  
Domestic Social Policy Division

### Summary

The spread of H5N1 avian influenza (“flu”) on three continents, and the human deaths it has caused, raise concern that the virus could morph and cause a global human pandemic. Congress has provided specific funding for pandemic flu preparedness since FY2004, including \$6.1 billion in emergency supplemental appropriations for FY2006. These funds bolster related activities to prepare for public health threats, and to control seasonal flu. This report discusses appropriations for pandemic flu, primarily to the Department of Health and Human Services (HHS), and will be updated as needed.

### Background

In 1997, a new avian (bird) flu virus emerged and jumped to humans in Hong Kong, killing six people. It has since spread to other countries in Asia, Europe and Africa, where it has infected more than 250 people, killing more than 150 of them. The situation has created concern that the virus could change sufficiently to launch a global human pandemic. Beginning in FY2004, and each year since, Congress has provided specific funding for pandemic flu preparedness, through both regular and emergency supplemental appropriations.

This report describes federal funding for pandemic flu preparedness, primarily to the Department of Health and Human Services (HHS). Federal funding to control avian flu in birds is generally provided to the U.S. Department of Agriculture (USDA) for activities involving commercial poultry, and the Department of the Interior for activities involving wildlife. The State Department and the U.S. Agency for International Development (USAID) have also received funds for global avian flu control efforts, as have the Departments of Homeland Security, Defense, and Veterans Affairs.<sup>1</sup>

---

<sup>1</sup> For more information, see CRS Report RL33795, *Avian Influenza in Poultry and Wild Birds*, by Jim Monke and M. Lynne Corn, and CRS Report RL33219, *U.S. and International Responses to the Global Spread of Avian Flu: Issues for Congress*, by Tiaji Salaam-Blyther.

Tracking federal funding for avian and pandemic flu preparedness is difficult for several reasons. First, funds designated specifically for pandemic flu do not reflect the sum of all relevant activities. For example, programs to improve health surveillance in general, or to streamline federal coordination during disasters, are important for pandemic preparedness. Also, the President has called on all federal agencies to develop continuity plans specifically for a flu pandemic, activities that are typically funded through general administrative accounts. Second, certain activities (e.g., the expansion of flu vaccine production capacity) address preparedness for both seasonal and pandemic flu, and may not be designated as pandemic spending, despite their relevance. Finally, federal agencies may not prepare budget information, such as the presentation of base funding or annual increases, in a consistent fashion.

This report provides information on appropriations, primarily to HHS, that the Congress has specifically designated for influenza preparedness, including efforts to expand seasonal flu vaccine production capacity and related activities. Amounts are discussed in subsequent sections of the report, and are presented in **Tables 1** and **2** at the end. Pandemic flu funding for HHS has generally been provided in the Public Health and Social Services Emergency Fund (PHSSEF), an account intended for one-time or short-term activities. This report will be updated as events warrant.<sup>2</sup>

## History of Recent Appropriations

**FY2004.** Specific appropriations for HHS pandemic flu activities were first provided by Congress in FY2004. In February 2003, the Administration requested \$100 million for activities to ensure an adequate supply of vaccine in the event of a pandemic.<sup>3</sup> In P.L. 108-199, the Consolidated Appropriations Act, 2004, Congress provided \$50 million to HHS for activities to enhance vaccine production capacity.<sup>4</sup> Funding was used in part to award a \$10 million contract to a domestic manufacturer of injectable flu vaccine to assure a year-round supply of eggs for vaccine production.<sup>5</sup>

**FY2005 — Regular Appropriations.** In February 2004, the Administration again requested \$100 million for HHS to expand vaccine production capacity.<sup>6</sup> In October 2004, while Congress was considering FY2005 appropriations, federal officials were notified of a production failure at a plant supplying half of the nation's supply of injectable seasonal flu vaccine. The resulting vaccine shortage focused nationwide

---

<sup>2</sup> For more information regarding pandemic flu preparedness in general, see CRS Report RL33145, *Pandemic Influenza: Domestic Preparedness Efforts*, by Sarah A. Lister.

<sup>3</sup> U.S. Department of Health and Human Services, *Budget in Brief, FY2004*, Feb. 2003, text on p. 94 and table on p. 96, at [<http://www.hhs.gov/budget/04budget/fy2004bib.pdf>].

<sup>4</sup> P.L. 108-199, 118 Stat. 251.

<sup>5</sup> See HHS, "Secretary Thompson Announces Contract to Secure Future Egg Supply for Flu Vaccines," press release, Nov. 9, 2004; and HHS, "Pandemic Influenza Funding Activities," Web page, at [[http://www.hhs.gov/ophep/ophec/PanFlu/procurement\\_activities.html](http://www.hhs.gov/ophep/ophec/PanFlu/procurement_activities.html)].

<sup>6</sup> HHS, *Budget in Brief, FY2005*, Feb. 2004, p. 102, at [<http://www.hhs.gov/budget/05budget/fy2005bibfinal.pdf>].

attention on the frailty of the flu vaccine production system.<sup>7</sup> At the same time, H5N1 avian flu was spreading through Southeast Asia, with a growing human death toll. In December 2004, Congress passed P.L. 108-447, the Consolidated Appropriations Act, 2005, providing HHS with the requested \$100 million to bolster flu vaccine production capacity, including the purchase of flu vaccine.<sup>8</sup>

**FY2005 — Supplemental Appropriations.** In May 2005, Congress passed P.L. 109-13, the Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Tsunami Relief, 2005, providing \$25 million to USAID for programs to control the global spread of avian flu, and stipulating that \$15 million of it be transferred to the Centers for Disease Control and Prevention (CDC).<sup>9</sup> The law also provided \$58 million to CDC to purchase flu countermeasures (vaccines and antiviral drugs) for the Strategic National Stockpile, and \$10 million to HHS for sewer improvements to support an expansion of the nation's only domestic production facility for injectable flu vaccine.<sup>10</sup>

**FY2006 — Regular Appropriations.** In February 2005, the Administration requested \$120 million for HHS for pandemic preparedness for FY2006, including continued efforts to expand vaccine production capacity.<sup>11</sup> In July 2005, the Administration requested an additional \$150 million to purchase and stockpile pandemic flu countermeasures, including antiviral drugs and prototype H5N1 vaccines.<sup>12</sup> In December 2005, Congress provided funding for pandemic flu in FY2006 emergency supplemental appropriations (discussed below), using this vehicle, rather than regular appropriations, to provide the bulk of pandemic funding for FY2006. Also in December 2005, Congress passed regular FY2006 appropriations for HHS in **P.L. 109-149**, the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2006, providing \$63.6 million to HHS for general public health preparedness activities, including, but not limited to, efforts to bolster domestic flu vaccine production capacity and to stockpile vaccine.<sup>13</sup>

**FY2006 — Supplemental Appropriations.** As Congress weighed regular appropriations for FY2006, H5N1 avian flu spread to Europe, and Hurricane Katrina raised concerns about the nation's general level of disaster readiness. In November 2005, the Administration requested \$7.1 billion in emergency supplemental funds for avian and

---

<sup>7</sup> See CRS Report RL32655, *Influenza Vaccine Shortages and Implications*, by Sarah A. Lister and Erin D. Williams.

<sup>8</sup> P.L. 108-447, 118 Stat. 3138. The act also provided \$300,000 above the budget request to the Food and Drug Administration (FDA), for flu vaccine activities.

<sup>9</sup> H.Rept. 109-72, p. 144.

<sup>10</sup> *Ibid.*, pp. 149-150.

<sup>11</sup> HHS, *Budget in Brief, FY2006*, Feb. 2005, text, p. 112, and table, p. 113, at [<http://www.hhs.gov/budget/06budget/FY2006BudgetinBrief.pdf>].

<sup>12</sup> White House Office of Management and Budget, Estimate No. 9, July 15, 2005, at [[http://www.whitehouse.gov/omb/budget/amendments/amendment\\_7\\_15\\_05.pdf](http://www.whitehouse.gov/omb/budget/amendments/amendment_7_15_05.pdf)].

<sup>13</sup> P.L. 109-149, 119 Stat. 2857-2858. Pursuant to Section 3801 of P.L. 109-148, this amount was subject to a 1% rescission.

pandemic flu preparedness.<sup>14</sup> This included \$6.7 billion for HHS, for amounts to be obligated over three years — \$3.2 billion for obligation in FY2006, \$2.3 billion for FY2007, and \$1.2 billion for FY2008 — and the remainder for FY2006 activities in several other departments and agencies. HHS amounts were intended primarily to promote the expansion of domestic vaccine manufacturing capacity.<sup>15</sup>

**First Supplemental.** In December 2005, Congress provided \$3.8 billion in emergency supplemental appropriations, including \$3.3 billion for HHS, in Division B, Title II of P.L. 109-148, the Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act, 2006. The distribution of these funds to various federal departments and agencies is presented in **Table 2**. Most of the shortfall between the \$7.1 billion request and the \$3.8 billion appropriation resulted because Congress did not fund the “out years” of the Administration’s HHS request for FY2007 and FY2008. Congress directed that HHS use the \$3.3 billion for FY2006 as follows:

- \$350 million to CDC for state and local public health capacity;
- \$50 million for CDC capacity;
- \$150 million to CDC for domestic and global surveillance;
- \$96 million to HHS for other international activities;
- \$20 million to the Food and Drug Administration (FDA); and
- \$2.654 billion for vaccine development and stockpiling.<sup>16</sup>

In report language (H.Rept. 109-359), conferees directed the Secretary of HHS to report to the Appropriations Committees on a semi-annual basis regarding the use of the \$3.3 billion provided. HHS has submitted a report to congressional appropriators<sup>17</sup> and posted three updates on these activities for public distribution.<sup>18</sup>

**Second Supplemental.** In its February 2006 FY2007 budget request, HHS repeated its November 2005 request of \$2.3 billion in FY2007 emergency supplemental funds for pandemic flu, but sought the funds prior to the regular FY2007 appropriations cycle. (HHS called the \$2.3 billion amount an “allowance.”)<sup>19</sup> In June 2006, Congress provided \$2.3 billion in supplemental funds to HHS in Title IV of P.L. 109-234, the

---

<sup>14</sup> White House Office of Management and Budget, Estimate No. 15, Nov. 1, 2005, at [[http://www.whitehouse.gov/omb/budget/amendments/supplemental\\_11\\_01\\_05.pdf](http://www.whitehouse.gov/omb/budget/amendments/supplemental_11_01_05.pdf)].

<sup>15</sup> Testimony of Michael O. Leavitt, Secretary of Health and Human Services, hearing on Pandemic Influenza before the House Committee on Appropriations, Subcommittee on Labor, Health and Human Services, and Education, Nov. 2, 2005, 109<sup>th</sup> Cong., 1<sup>st</sup> Sess.

<sup>16</sup> See P.L. 109-148, 119 Stat. 2783 for amounts to FDA, which is funded through Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations, and 119 Stat. 2786-2787 for the remaining HHS activities.

<sup>17</sup> HHS, Report to Congress, “Pandemic Influenza Preparedness Spending, Conference Report 109-359,” June 15, 2006.

<sup>18</sup> See HHS, Pandemic Planning Updates I, II, and III, at [<http://www.pandemicflu.gov/plan/tab1.html>].

<sup>19</sup> HHS, *Budget in Brief, FY2007*, Feb. 2006, pp. 99-101, at [<http://www.hhs.gov/budget/07budget/2007BudgetInBrief.pdf>].

Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Hurricane Recovery, 2006.<sup>20</sup> No other departments or agencies received funds specifically for avian or pandemic flu in the act. (See **Table 2.**) Congress authorized the Secretary of HHS to use most of the funds to further federal domestic preparedness activities, the vaccine initiative (including the construction or renovation of privately owned buildings), and stockpiling of antiviral drugs and medical supplies. Congress directed that HHS use portions of the funds as follows:

- \$30 million for international disease control, through USAID;
- \$250 million to CDC for state and local public health capacity; and
- at least \$200 million for CDC capacity.

**FY2007.** In February 2006, in addition to the supplemental funds discussed above, the Administration requested \$352 million in regular appropriations for HHS pandemic flu activities.<sup>21</sup> In June and July 2006, respectively, the House and Senate Committees on Appropriations reported FY2007 appropriations for HHS, including amounts targeted for pandemic preparedness. Shortly before emergency supplemental appropriations were enacted in June, the House committee provided \$78.9 million in regular FY2007 appropriations for HHS, through the PHSSEF.<sup>22</sup> The committee did not provide requested amounts for several specific agency programs, noting that Congress was weighing the supplemental spending bill at the time. In July, after supplemental appropriations were enacted, the Senate committee also provided \$78.9 million for the PHSSEF and the following additional amounts for pandemic preparedness:

- \$24.7 million to CDC's Infectious Diseases Control budget;
- \$8 million to CDC's Health Marketing budget, for risk communication;
- \$59 million to CDC's Global Health budget, for disease detection.<sup>23</sup>

In May 2006, the House passed Agriculture appropriations for FY2007, including \$28.1 million for pandemic flu activities at FDA.<sup>24</sup> In June, the Senate committee reported Agriculture appropriations, including a \$50.5 million increase for FDA pandemic flu activities, to make the FY2007 total in excess of \$60 million.<sup>25</sup>

Further congressional action on FY2007 appropriations for HHS, including FDA, is pending.

**FY2008.** As discussed earlier, the Administration requested, in November 2005, \$7.1 billion in supplemental funds for pandemic preparedness, of which \$1.16 billion was to be available to HHS in FY2008. Congress has not provided appropriations for the

---

<sup>20</sup> P.L. 109-234, 120 Stat. 479-480.

<sup>21</sup> HHS, *Budget in Brief, FY2007*, Feb. 2006, pp. 99-101.

<sup>22</sup> H.Rept. 109-515, June 20, 2006, p. 169.

<sup>23</sup> S.Rept. 109-287, July 20, 2006, pp. 7, 90, 96, and 221.

<sup>24</sup> H.Rept. 109-463, May 12, 2006, p. 115.

<sup>25</sup> S.Rept. 109-266, June 22, 2006, p. 144. Amounts reported include some carryover of the \$20 million provided in the first supplemental, P.L. 109-148.



## CRS-6

requested amount for FY2008. The Administration may repeat its request for this amount, or request other amounts, in its budget proposal for FY2008, expected in February 2007.

**Table 1. HHS Appropriations Targeted for Pandemic Flu**  
(dollars in millions)

| <b>Funding mechanism</b>    | <b>FY2004</b> | <b>FY2005</b>     | <b>FY2006 enacted</b> |
|-----------------------------|---------------|-------------------|-----------------------|
| Regular appropriations      | \$50          | \$99 <sup>a</sup> | \$64 <sup>c</sup>     |
| Supplemental appropriations | 0             | 83 <sup>b</sup>   | 5,620                 |
| <b>TOTAL</b>                | <b>50</b>     | <b>182</b>        | <b>5,684</b>          |

a. Reflects a 0.8% rescission.

b. Includes \$15 million transferred to CDC from USAID.

c. Amount is not restricted to avian and pandemic flu activities.

**Table 2. FY2006 Supplemental Appropriations for Avian and Pandemic Flu**  
(dollars in millions)

| <b>Department or Agency</b> | <b>Supplemental request<sup>a</sup></b> | <b>P.L. 109-148</b>     | <b>P.L. 109-234</b> |
|-----------------------------|-----------------------------------------|-------------------------|---------------------|
| Agriculture                 | \$91.4                                  | \$91.4                  | 0                   |
| Defense                     | 130.0                                   | 130.0                   | 0                   |
| HHS                         |                                         |                         |                     |
| (Request for FY2006)        | (3,200.0 <sup>b</sup> )                 | (3,320.0 <sup>b</sup> ) | 0                   |
| (Request for FY2007)        | (2,300.0)                               | 0                       | (2,300.0)           |
| (Request for FY2008)        | (1,160.0)                               | 0                       | 0                   |
| Total for three years       | 6,660.0 <sup>b</sup>                    | 3,320.0 <sup>b</sup>    | 2,300.0             |
| Homeland Security           | 47.3                                    | 47.3                    | 0                   |
| Interior                    | 11.6                                    | 11.6                    | 0                   |
| State                       | 38.5                                    | 31.0                    | 0                   |
| Veterans Affairs            | 27.0                                    | 27.0                    | 0                   |
| USAID                       | 131.5                                   | 131.5                   | 0                   |
| <b>TOTAL</b>                | <b>7,137.3</b>                          | <b>3,789.8</b>          | <b>2,300.0</b>      |

a. White House Office of Management and Budget, Estimate No. 15, Nov. 1, 2005, at [[http://www.whitehouse.gov/omb/budget/amendments/supplemental\\_11\\_01\\_05.pdf](http://www.whitehouse.gov/omb/budget/amendments/supplemental_11_01_05.pdf)].

b. Includes \$20 million for FDA, provided in Agriculture appropriations.

# Exhibit N

**Pandemic Influenza Guidance Supplement to the  
2006 Public Health Emergency Preparedness  
Cooperative Agreement  
Phase II**

**Date: July 10, 2006**

## TABLE OF CONTENTS

|                                                                                            |           |
|--------------------------------------------------------------------------------------------|-----------|
| <b>Supplemental Guidance .....</b>                                                         | <b>3</b>  |
| Availability of Funds.....                                                                 | 3         |
| Purpose.....                                                                               | 3         |
| Background.....                                                                            | 5         |
| Application Content & Required Activities.....                                             | 8         |
| Additional Requirements.....                                                               | 13        |
| Funds to Local Public Health.....                                                          | 13        |
| Cost Sharing or Matching.....                                                              | 14        |
| Tribes.....                                                                                | 14        |
| Allowable Cost.....                                                                        | 14        |
| Unallowable Cost.....                                                                      | 14        |
| Supplantation.....                                                                         | 15        |
| Financial Management System Requirements.....                                              | 15        |
| Grants Subcontracting that Spans Budget Periods.....                                       | 15        |
| <b>CDC Responsibilities.....</b>                                                           | <b>15</b> |
| <b>Attachments.....</b>                                                                    | <b>20</b> |
| A– Performance Measures for FY 2006 Pandemic Influenza Emergency Supplemental Funding..... | 20        |
| B– List of Critical Tasks organized by Pandemic Flu Goals and Target Capabilities...       | 26        |
| C – Pandemic Influenza Work Plan Logic Model.....                                          | 36        |
| D – 2006 Pandemic Influenza Work Plan Guidance and Examples.....                           | 37        |
| E – 2006 Pandemic Influenza Work Plan Step-by-Step Instructions.....                       | 43        |
| F – FY 2006 Funding Distribution Table.....                                                | 47        |

## Supplemental Guidance for Pandemic Influenza

**I. Availability of Funds:** Approximately \$225,000,000 is available to fund pandemic influenza preparedness activities specifically intended to develop and exercise pandemic influenza plans. Applicants should submit a letter requesting the amount indicated on the attached pandemic influenza supplement funding table with their PHEPCA continuation applications on July 15. Funds will be added to the PHEPCA continuation and 20% may be obligated or expended by your agency pending receipt of a request for redirection of the pandemic influenza Phase II funds as part of this application which is due August 31, 2006

**Eligibility Information:** Eligibility is limited to entities currently funded through Cooperative Agreement AA154 and authorized under 42 U.S.C. 247d-3. This includes all 50 states, five territories (Puerto Rico, the U.S. Virgin Islands, American Samoa, Commonwealth of the Northern Mariana Islands, and Guam), and three Freely Associated States (Republic of the Marshall Islands, Republic of Palau, and the Federated States of Micronesia), the localities of Chicago, Los Angeles County, New York City, and Washington, D.C.

**II. Purpose:** This document provides supplemental guidance for recipients of federal funding through the *Public Health Preparedness and Response Cooperative Agreement* (Cooperative Agreement AA154) for the purpose of furthering pandemic influenza preparedness and response.

Congress appropriated \$350,000,000 in emergency supplemental funding for pandemic influenza preparedness activities specifically intended to foster developing and exercising pandemic influenza plans. Specifically, the *Congressional Record* states, “The conference agreement includes bill language designating \$350,000,000 for upgrading State and local response capacity, particularly the planning and exercising of pandemic response plans by State and local officials. Section 8116 of the Senate bill proposed \$600,000,000 for this activity. The conferees are aware that any successful response to a pandemic influenza must include an effective response at the State and local levels. This will require pre-established partnerships and collaborative planning by public health officials, law enforcement officials, hospital administrators, and community leaders, who have considered a broad range of scenarios and participated in realistic response exercises. These planning and response exercises should enable public health and law enforcement officials to establish procedures and locations for quarantine, surge capacity, diagnostics, and communication. The conferees intend that most of these funds be put toward planning and exercises. The conferees intend that these funds be provided accompanied by established benchmarks and that a portion of the funding be

made available based on meeting performance objectives at both the State and local levels.”

This funding supports key elements of the *National Strategy for Pandemic Influenza*, the *Implementation Plan for the National Strategy* and the *HHS Pandemic Influenza Plan*.

Funding is being awarded in phases. In Phase I, \$100,000,000 was awarded to recipients on March 8, 2006. Recipients were required to use assessment tools developed by the Centers for Disease Control and Prevention (CDC) to identify gaps in their pandemic influenza planning and establish an approach for filling those gaps. The remaining \$250,000,000 is being divided into a \$225,000,000 formula award and a \$25,000,000 competitive award. This announcement (for Phase II) provides \$225,000,000 to recipients contingent upon sufficient responses to certain program requirements discussed below. The balance -- \$25,000,000 -- will soon be awarded competitively to eligible recipients.

Projects supported by this cooperative agreement should be fully prepared to respond to and control a pandemic influenza outbreak by the end of three budget years, beginning with the initial funding under this supplement, but accelerated if epidemiologic information suggests the need to implement a cohesive response prior to that time. CDC endorses capabilities-based disaster planning and exercising consistent with the Homeland Security Exercise and Evaluation Program (HSEEP) – a national exercise program coordinated by the Department of Homeland Security (DHS).

In addition to the intent of the Congressional conference report, Secretary Leavitt has articulated in his Pandemic Influenza summits across the country that medical care providers will be on the front lines of the pandemic to provide care to the population. A component of this Pandemic Influenza Supplement should be used to augment the funding provided by the Health Resources and Services Administration (HRSA) National Bioterrorism Hospital Preparedness Program (NBHPP) to fill the gaps identified in the NBHPP Pandemic Influenza Scenario to address healthcare infrastructure preparedness and medical surge needs. This tiered healthcare system, detailed in the FY06 NBHPP Cooperative Agreement Guidance<sup>1</sup>, should then be exercised in coordination with public health, emergency management, homeland security, and other response partners to ensure that gaps are adequately addressed.

Activities proposed for funding under this guidance, and undertaken via approved applications, are to be coordinated by the Senior Advisory Committee which is uniformly described in the CDC-PHEP, HRSA-NBHPP, and Homeland Security Grant Program (HSGP) guidance documents<sup>2</sup>.

<sup>1</sup> <http://www.hrsa.gov/bioterrorism/>

<sup>2</sup> The membership of the Senior Advisory Committee must, at a minimum, include the following State officials directly responsible for the administration of Office of Grants and Training grants and CDC and

Recipients are reminded that any continuation of funding under this cooperative agreement is contingent upon responsiveness to the program guidance, successful completion of the activities submitted in the application in response to Critical Tasks, measured progress in meeting the Performance Measures, and proper stewardship of these congressionally-appropriated funds. Progress on actual tasks proposed in the application will be routinely assessed by the project officers and subject matter experts, and formal Progress Reports will be required twice in the budget year. In addition to the six pandemic influenza-specific Performance Measures in this document, data will be collected on the 23 Performance Measures that are described in the base Public Health Emergency Preparedness Cooperative Agreement (PHEPCA). Performance Measures are macro indicators that the public health system's response is improving in flexibility, scalability, and effectiveness. The completion of Critical Tasks as described in the application will facilitate community efforts to implement various interventions to combat an influenza pandemic. Incomplete or otherwise inadequate plans, as determined by CDC subject matter experts, will result in funding restrictions at the time of award until the flaws are remedied.

**III. Background:** Earlier this year, U.S. Department of Health and Human Services (HHS) Secretary Michael O. Leavitt and the nation's Governors led a series of State Pandemic Influenza Summits. The objectives were to enhance awareness of about the likely consequences of an influenza pandemic, to emphasize how seriously under-prepared the United States is at all levels of government and throughout the private sector, to improve understanding of the unique but necessarily limited roles that the Federal Government can play in countering a pandemic, and to stimulate community-wide preparedness initiatives by governments, individuals, businesses, and community organizations. The Summits were uniformly successful in sparking calls to action to improve pandemic preparedness across the nation. The challenge now is to use the momentum from the Summits to energize local-, tribal-, territorial-, and state-level initiatives to undertake those preparedness tasks that communities must do themselves.

To that end, the influenza-specific supplemental funds that are the subject of this guidance provide state, territorial, and local public health officials substantial new financial resources with which to spearhead and catalyze pandemic preparedness initiatives throughout their jurisdictions while they continue to create and sustain

---

HRSA cooperative agreements: the State Administrative Agency (SAA), HRSA Program Director, HRSA Bioterrorism Hospital Coordinator, and CDC Program Director. In addition, program representatives from the following entities should be members on the committee: State Homeland Security Advisor (if this role is not also the SAA); State Emergency Management Agency Director; State Public Health Officer; State Public Safety Officer (and SAA for Justice Assistance Grants, if different); State Court Official; State EMS Director; State Trauma System Manager; State Citizen Corps POC; United States Coast Guard Area Command or Captain of the Port; Senior Members of the Regional Transit Security Working Group, Senior Security Officials from Major Transportation Systems; and the Adjutant General.



emergency-ready public health agencies. HHS looks to state, territorial, tribal, and local public health officials to follow the examples of their respective Governors and Secretary Leavitt and demonstrate leadership in moving all facets of their communities toward pandemic influenza preparedness.

As with the base PHEPCA, this supplement organizes Critical Tasks under a series of Capabilities. Capabilities are combinations of people, equipment, and supplies which, through proper planning, equipping, training, organizing, and exercising, can perform Critical Tasks at expected levels of proficiency to achieve desired Outcomes in response to national disasters. The nation has defined 37 Target Capabilities as an element in Homeland Security Presidential Directive 8 – National Preparedness guidance implementation. These Capabilities, in varying degrees of aggregation, are brought to bear to accomplish the necessary tasks to prevent, protect against, respond to and recover from catastrophic events.

Public health is primarily responsible for, or has significant interest in, at least two thirds of the Target Capabilities. Because some events occur rarely, drills and exercises are required to maintain response proficiency. Routine public health activities provide opportunities for practice, but large-scale disasters involve multitudes of responders interacting in non-typical ways. Drills and exercises permit individuals and organizations to carry out their normal duties and relate to each other under unusual circumstances in simulated environments that are far less costly and threatening than real events. CDC's Coordinating Office of Terrorism Preparedness and Emergency Response (COTPER) will evaluate awardees' preparedness through drills and exercises.

Preparedness begins with plans to control hazards and reduce vulnerabilities ("Hazards and Vulnerability Analysis"-HVA) that cannot be eliminated entirely. Emergency response plans ("plans") describe what well-trained, equipped, and supplied responders ("capacity") must be able to do ("capability") to minimize injuries, deaths, and damage from uncontained hazards. Discussion-based exercises (e.g., tabletop exercises) help identify "gaps" in the plan (i.e., partners [Note: Important given the example below.], policies, protocols, processes, and procedures) which are overlooked or not sufficiently addressed in the plan. Such gaps must be filled before expensive, resource-intensive operations-based drills and exercises are conducted. For example, how children will be educated at home if schools are closed should be determined before a full-scale exercise. As responders practice the plan through exercising, they learn which aspects of response do not "go as planned." After the exercise, responders debrief ("hot wash") and create an After-Action-Report (AAR). It is not enough to record the lessons learned from the exercises. Responders must also describe corrective actions to fix response problems, including who is responsible for fixing what by when ("Corrective Action Plan"). Proposed solutions must be re-tested to ensure that they adequately correct the response problem. If the solutions are good, the plan is amended to incorporate the new information. The result is improved ability to respond to hazards that can become uncontrolled, or new knowledge

that reduces the risk posed by the hazard. Sometimes discoveries made during exercises result in strategies that eliminate hazards altogether or render populations invulnerable to them, which shortens the Hazards and Vulnerability list.

This supplement to the Public Health Emergency Preparedness cooperative agreement strives to improve understanding of 1) Target Capabilities, 2) Tasks deemed critical by science and expert opinion under each Capability, 3) Performance Measures for Tasks that require monitoring, and 4) Actions that detail steps that should be implemented to accomplish a Task. (See Attachment C.)

The Phase I Pandemic Influenza Supplement assessment tools provided states, cities, and territories with an opportunity to identify their pandemic influenza planning gaps based on 60 Critical Tasks. These tasks are organized under nine of the 37 Target Capabilities identified by the DHS. An updated, refined version of these Critical Tasks is Attachment B (List of Critical Tasks Organized by Pandemic Flu Goals, Target Capabilities). Because of the comprehensive nature of pandemic influenza planning and response, the range of possible Critical Tasks necessary to fill gaps may exceed those listed on the assessment tools. Recipients should work from the current, refined list of Critical Tasks (See Attachment B) and may develop additional Critical Tasks to best address the gaps unique to their pandemic influenza planning status.

For the year 2006-2007, recipients must address a total of five Target Capabilities. These are linked to the four high level priorities that are identified in this (Phase II of the Pandemic Influenza Emergency Supplemental) guidance document: State and Local Pandemic Influenza Preparedness Assessments, Pandemic Influenza Exercise Program, Antiviral Drug Distribution Plan, and State Pandemic Influenza Preparedness Plan. These priorities fall within four Target Capabilities: Planning, Medical Surge, Mass Prophylaxis, Isolation and Quarantine. A fifth Target Capability, Communications, is tied to a performance measure on the Public Health Information Network (PHIN). Thus this year recipients must address a total of five Target Capabilities and relevant Critical Tasks based on gaps (see Attachment B)

As part of their application, recipients should also prioritize the remaining four Target Capabilities (Epidemiological Surveillance and Investigation, Public Health Laboratory Testing, Emergency Public Information and Warning, and Community Preparedness and Participation) based on the number and severity of gaps identified under each Target Capability.

In year two, recipients should prioritize in the same manner all remaining Critical Tasks under the remaining four Targeted Capabilities, provide a detailed work plan for the next two highest priority Target Capabilities, and implement the work plan.

In year three, recipients should prioritize by number and severity of gaps the two remaining Target Capabilities, develop a work plan for the Critical Tasks with gaps and implement the work plan.

Attachment C displays a logical framework demonstrating how recipients can work towards achieving their priority Target Capabilities. To achieve a CDC Goal, recipients must attain at least one Target Capability. Each Target Capability in turn, has at least one Critical Task associated with it. To accomplish the Critical Task, the recipient should conduct at least one or more Action Items. Each Action Item will be associated with Outputs as well as targets and measures. This sets up a logical framework to attain progress.

Historically, recipients have described their Action Items (activities) using a process driven (or narrative) approach. This made it difficult to track and monitor while assessing the ultimate impact of recipient efforts on Critical Tasks and Target Capabilities. In the absence of a logical framework that linked recipient efforts to CDC Goals, the achievement of these Goals was essentially a “leap of faith.” The proposed approach addresses these limitations by allowing recipients to deductively and inductively think through and develop their work plan using a framework which starts with a CDC Goal and ends with a set of Action Items and associated Outputs.

More specifically, the framework allows recipients to describe and monitor their work using predefined descriptive elements (what, when, where, who, how) in conjunction with self-defined, discrete Output measures. These measures are collectively referred to as Success Factors. Note that while the framework describes a way to link Action Items to both Outcome and Output measures, Grantees are only required to provide Output measures for each of their Action Items.

Attachment D provides a template that recipients should fill out to demonstrate this logical relationship in the context of their work plan. The attachment also provides two examples of what a work plan might look like for the Mass Prophylaxis Target Capability. If the Target Capability is linked to a Standard CDC Performance Measure (Attachment A), the measure should be specified when filling out the template.

#### **IV. Application Content and Required Activities:**

Recipients must submit a jurisdiction-wide work plan to address the requirements in this announcement and comply with all of the requirements for Phase I as well as the 2006 Public Health Preparedness Cooperative Agreement. Activities should be carried out by the recipient in collaboration with community partners such as DHS-funded Metropolitan Medical Response System (MMRS) Steering Committees and Urban Area Security Initiative (UASI) Working Groups (for

communities so situated)<sup>3</sup>, as well as Medical Reserve Corps, private businesses, schools, Citizen Corps/ community citizens, hospitals and other healthcare entities and coordinated by the Pandemic Influenza Coordinating Committee.

Work Plan Development:

As part of this application, recipients will develop work plans using the framework outlined in Attachment C for all Action Items targeting the five priority Target Capabilities. It is mandatory for recipients to address Target Capabilities 1-4 because they correspond to the three priorities as highlighted in the Phase II Pandemic Influenza Guidance noted above. In addition, it is mandatory for recipients to address the Target Capability for Communication because it ties in directly with the Performance Measure that relates to PHIN standards/certification.

As part of the 2006 work plan, recipients must also prioritize the remaining four Target Capabilities (Epidemiological Surveillance and Investigation, Public Health Laboratory Testing, Emergency Public Information and Warning, and Community Preparedness and Participation) based on the number of gaps identified under each Target Capability.

In year two, recipients should prioritize Critical Tasks for the next two highest priority Target Capabilities (as identified by recipients) and implement the work plan to address gaps.

In year three, recipients should prioritize the Critical Tasks for the two remaining Target Capabilities, develop a work plan for Critical Tasks with gaps and implement the work plan.

Please refer to Attachment D for step by step instructions on how to develop the work plan.

Reporting Progress:

During the course of the year, recipients will report on the progress made for Action Items falling under the five Target Capabilities as part of their midyear and end-of-year progress reports. Progress reports will comprise updates on the extent to which Output Targets are achieved and a brief description of barriers encountered in achieving these targets.

In years two and three, recipients will implement Action Items for the remaining Target Capabilities. In addition, as part of the mid year and end of year progress reports, they will report on the progress made in achieving the Output Targets.

---

<sup>3</sup> The FY06 Homeland Security Grant Program guidance is available at <http://www.ojp.usdoj.gov/odp/docs/fy2006hsgp.pdf>

**1. Priority: State and Local Pandemic Influenza Preparedness Assessments (Target Capability: Planning)**

- a. Objectives for the budget period (08/31/06-08/30/07): Work with colleagues in homeland security and emergency management, healthcare and community partners to develop and implement a jurisdictional work plan to address gaps – beginning with those which are high priorities – in community-wide pandemic influenza preparedness; conduct a follow-up assessment (utilizing Phase I assessment tools: Attachment 4a, Self Assessment—State Public Health, Attachment 4b, Self Assessment—Local Public Health, and Attachment 4c, Self Assessment—Local Public Health Totals) to determine progress and create a new priorities list to direct future work.

Application content: Each of the three items below is required to constitute a sufficient application.

i. Assessment results:

1. Describe and analyze the results of the state pandemic influenza assessment data and local pandemic influenza assessment data;
  2. Present a prioritized list of the gaps identified by the results of the data analyses noted above, and identify how and why each gap was selected as a priority.
- ii. A work plan (with timelines) for addressing the highest priority gaps—as identified under the nine Target Capabilities—in community pandemic influenza preparedness; and,
- iii. Associated budget, utilizing Attachment C, Critical Tasks, to inform the activities required to address each identified priority gap.

b. Post-award milestones and deadlines:

- i. April 15, 2007: First progress report due
- ii. July 30, 2007: Follow-up assessment and data analysis complete
- iii. November 30, 2007: Final progress report due

**2. Priority: Pandemic Influenza Exercise Program (Target Capabilities: Isolation and Quarantine, Medical Surge, and Mass Prophylaxis)**

Objectives for the budget period (08/31/06-08/30/07): Develop and implement a pandemic influenza preparedness exercise program to include (at least) the three priority pandemic influenza preparedness exercises prescribed below. The exercises should be conducted throughout the budget period and involve community partners. Wherever feasible, these

exercises should be combined with already scheduled exercises directed by homeland security, emergency management, or other officials, to minimize the total burden on exercise planners and participants. Where appropriate CDC and HRSA will collaborate to provide subsequent guidance including objectives, suggested participants, format, process, data to be gathered, reporting, and after action steps.

- i. Non-pharmacological interventions and a community containment plan to help contain the spread of pandemic influenza – with emphasis on school closing decisions and discouragement of large public gatherings;
- ii. Medical surge to accommodate influenza victims; and,
- iii. Seasonal influenza vaccination clinics to exercise mass prophylaxis capabilities, including points-of-dispensing (PODs).

b. Application content: A 12-month timeline for the envisioned exercise program (The pandemic influenza exercise program plan should include the budget period objectives, anticipated participants, format, data to be gathered, and plan to create an after-action report and implement recommendations.

c. Post-award milestones and deadlines:

- i. Fall 2006: Conduct exercises with seasonal influenza vaccination clinics;
- ii. November 30, 2006: Submit the community containment plan and accompanying exercise to be used to test the plan
- iii. February 15, 2006: Complete 50% of the other envisioned exercises.

### **3. Priority: Antiviral Drug Distribution Plan (Target Capability: Mass Prophylaxis)**

- a. Objectives for the budget period (08/31/06-08/30/07): Develop and test an antiviral drug distribution plan describing the receipt, intrastate distribution, storage, security, monitoring, allocation, and administration of antiviral drugs provided by the Strategic National Stockpile (SNS) or state stockpiles, as appropriate. Ensure that the dispensing of local/metropolitan regional caches (especially those funded by the HRSA NBHPP, CDC-PHEP, and Homeland Security Grant Program [particularly the MMRS and UASI components]) is taken into account. The Public Health Information Network- (PHIN-) compatible information systems should be available and used to support allocation, distribution and administration of pandemic influenza countermeasures. Ensure that plans address distribution from the site of SNS delivery to the



terminal foci in or near healthcare settings identified in Phase I of the pandemic influenza supplemental emergency funds. Antivirals from the SNS that are distributed to states for hospitals are intended for the care of hospital personnel, patients and family members only. Hospital facilities are not to be considered as points of dispensing (PODs).

A model work scope between states and private distribution contractors to perform the intrastate distribution of antiviral drugs will be sent to awardees within a week of the release of this guidance document. This is meant to provide one model for states, and is not meant to be prescriptive; however, it does highlight many of the Critical Tasks involved in the process of intrastate distribution of antiviral drugs.

- b. Application content: A summary and timeline of planned steps to develop the antiviral drug distribution plan, including the community partners who will be involved in assuring distribution and administration to the terminal foci in or near healthcare settings.
- c. Post-award milestones and deadlines:
  - i. November 30, 2006: Complete antiviral drug distribution plan
  - ii. August 30, 2007: Updated antiviral drug distribution plan as necessary based on lessons learned and retests after incorporating the lessons learned throughout budget period.

#### **4. Priority: State Pandemic Influenza Preparedness Plan<sup>4</sup> (Target Capability: Planning)**

- a. Objectives for the budget period (08/31/06-08/30/07): Complete and submit a state pandemic influenza response plan. [Note: This should be the entire plan, not just the health chapter.] In November 2005, the White House published the *National Strategy for Pandemic Influenza*, followed by the *National Strategy for Pandemic Influenza Implementation Plan* in May 2006. The *Implementation Plan* tasks federal departments (HHS and DHS) to work together to review and approve the state pandemic influenza response plans by May 2007 to ensure that various topics (e.g., non-pharmacological interventions, countermeasure distribution, public safety) are adequately addressed.
- b. Application content: Timeline of events to accomplish plan completion and submission by February 1, 2007.

---

<sup>4</sup> Applies only to 50 U.S. states and the District of Columbia



c. Post-award milestones and deadlines:

February 1, 2007: Submit state pandemic influenza response plan (e.g. countermeasure distribution, public safety, non-pharmaceutical interventions, transportation).

**5. Continuation of Prior Requirements**

Recipients are expected to comply with all of the requirements listed in the Pandemic Influenza Emergency Supplement: Phase I (published March 14, 2006) as well as the PHEPCA (published June 1, 2006). Please refer to previously released guidance documents.

**V. Additional Requirements:**

**1. Funds to Local Public Health and Healthcare Entities:**

- a. Due to the pervasive nature of an influenza pandemic, local communities/jurisdictions should take a leading role in preparedness and response, rather than relying solely on substantial outside aid, mutual support, or federal assistance. The local level is where the effects of the pandemic will be felt and where the response needs to occur. Therefore it is expected that the majority of these funds will be distributed to and utilized at the local level. Where the state health department serves as the provider of local public health services in areas not covered by a local health department, funds should be dispersed commensurate with that effort.
- b. CDC requires that the cooperative agreement application describes how the State health department engages local health departments to reach consensus, approval, or concurrence for the proposed use of non-earmarked cooperative agreement funds. The description should bear evidence that local health department officials have been engaged in the cooperative agreement process and at least a majority, if not the total, approves or concurs with the application itself. This evidence may be demonstrated by:
  - i. Consensus of a majority of local health officials whose collective jurisdictions encompass a majority of the State's population;
  - ii. Recommendation of the President of the State Association of County and City Health Officials (SACCHO) if a majority of local health officials whose collective jurisdictions encompass a majority of the State's population agree with the SACCHO's decision; OR

- iii. Any other alternative method agreed to by the State Health Official and a majority of local health officials whose collective jurisdictions encompass a majority of the State's population.

State recipients will be required to submit a list of concurring local health departments and a brief description of the process used to engage local health departments to reach consensus, approval, or concurrence for the proposed use of funds. In addition, State recipients will be required to provide signed letters of concurrence upon request.

2. **Cost Sharing or Matching:** Matching funds are not required for this program.
3. **Tribes:** CDC requires documentation with this cooperative agreement application that describes the process used by the applicant to engage American Indian tribal governments, Tribal organizations representing those governments, tribal epidemiologic centers, or Alaska Native Villages and Corporations located within their boundaries in reaching consensus, approval, or concurrence for the proposed use of non-earmarked cooperative agreement funds for pandemic influenza preparedness
4. **Allowable Costs**  
Many additional Critical Tasks that are relevant to pandemic influenza planning, exercise and response may be found in the greater PHEPCA and NBHPP cooperative agreements. New supplies and equipment such as personal protective equipment, safety syringes, ventilators, etc., are allowable purchases. Costs associated with Pandemic Influenza Summits conducted prior to the award are allowable expenses and should be coordinated with the NBHPP to avoid duplication and costs. While these funds may be used to either retain staff or expand staff resources, applicants are reminded that these are emergency supplemental funds.
5. **Unallowable Costs**
  - Purchase of antiviral drugs, seasonal influenza vaccine, or pneumococcal vaccine is not allowed from this supplemental allocation. PHEPCA and NBHPP funds may be used to establish pharmaceutical caches which can include prophylaxis, antibiotics, and antivirals<sup>5</sup>. PHEPCA-funded caches for public health first responders and their families.
  - The state, territorial, or local government is responsible for assuring that any local affiliate does not engage in research. For the definition of research, please see the CDC web site at the following Internet address: <http://www.cdc.gov/od/ads/opspoll1.htm>

<sup>5</sup> See page 10 of the 2006 PHEPCA at <http://www.bt.cdc.gov/planning/coopagreement/#fy06>

- Purchase of vehicles of any kind is not allowed.
- Pandemic Influenza Supplemental funds may not be used to purchase incentive items.

**6. Supplantation:** Cooperative agreement funds cannot supplant any current State or local expenditures. The Public Health Service Act, Title I, Section 319C (e) (42 USC 247d-3(e)) specifically states: "SUPPLEMENT NOT SUPPLANT. -- Funds appropriated under this section shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities under this section." Therefore, the law strictly and expressly prohibits supplantation.

**7. Financial Management Systems Requirements**

**A state, territory or local health agency must expend and account for grant funds in accordance with State laws and procedures for its own funds. 45 CFR Part 92.20.**

**8. Grants Subcontracting that Spans Budget Periods:** The Procurement and Grants Office (PGO) has provided guidance for contracts let by recipients that span budget periods under grants or cooperative agreements. This guidance may be found at [http://pgo.cdc.gov/pgo/webcache/Regulations/GIL\\_06004\\_Grant\\_Contracting\\_that\\_Spans\\_Budget\\_Periods2.pdf](http://pgo.cdc.gov/pgo/webcache/Regulations/GIL_06004_Grant_Contracting_that_Spans_Budget_Periods2.pdf)

**V. CDC Responsibilities:**

In a cooperative agreement, the CDC staff is substantially involved—beyond routine monitoring—in program oversight and support. CDC activities for this pandemic influenza cooperative agreement supplement are as follows:

1. Fulfill federal-level obligations to achieve CDC's Draft Pandemic Influenza Preparedness Goals (e.g., "Increase use and development of clinical, non-pharmaceutical, and risk communications interventions known to minimize the spread of influenza").
2. Ensure that all of CDC's pandemic influenza activities that support local, tribal, territorial, and state jurisdictions' pandemic influenza activities are coordinated internally (within CDC) and externally (with other federal agencies and departments and non-government entities).
3. Provide pandemic influenza preparedness and response technical assistance including, but not limited to:
  - a. Developing, piloting, and evaluating standardized, valid drills and exercises and/or requirements and instructions for conducting such drills and exercises;

- b. Conducting evaluations (e.g., cost-effectiveness, Outcome) of local, tribal, territorial, and state pandemic influenza preparedness activities and identifying and disseminating results and promising practices;
  - c. Integrating/coordinating federal funding for local, tribal, territorial, and state pandemic influenza preparedness; and,
  - d. Disseminating subject matter expertise on pandemic influenza and related preparedness activities including evaluation, laboratory testing, epidemiology and surveillance, continuous quality improvement, communications, training, stockpile preparedness, and information systems and informatics.
- 4. Evaluate the technical assistance (under Responsibility 3) and program assistance (i.e., that provided by Project Officers) delivered to local, tribal and state jurisdictions.
- 5. Develop appropriate performance goals, science-based standards and measures, and valid and reliable assessment and evaluation instruments.
- 6. Provide guidance on, and in some cases, conduct drills and exercises, consistent with HSEEP, including objectives, suggested participants, format, process, data to be gathered, reporting, and after action steps. Where appropriate, CDC and HRSA will collaborate to create guidance and provide technical assistance.
- 7. Review critically, using CDC and non-CDC subject matter (e.g., operations, logistics, influenza, evaluation, laboratory) experts, the applications to include a critique narrative, assessments, year-long exercise plan, antiviral drug distribution plan, the budget to support the three priorities and related five Target Capabilities for this pandemic influenza supplement. Incomplete or otherwise inadequate plans will result in funding restrictions at the time of award and until the deficiencies are remedied.
- 8. Review critically, using CDC and non-CDC subject matter experts, progress reports to ensure technically acceptable and timely performance, program spending to ensure fiscal accountability, amount of local-level spending, and swift use of emergency supplemental funds, and recipients' evidence demonstrating that all Critical Tasks are being implemented, monitored, and evaluated on an on-going basis. Continuation of funding under this cooperative agreement is contingent upon responsiveness to the program guidance, measured progress in meeting the Performance Measures, and proper stewardship of these congressionally-appropriated funds.

9. Facilitate the inclusion of tribal, military, international, and federal (e.g., DHS) activities into national pandemic influenza preparedness efforts.

## **VII. Submission Information**

**A. Electronic applications using the CDC-provided template are due on August 31, 2006 11:59 pm EST. Note: The budget and work plan template will be made available under the “File Download” section of the MIS homepage. Guidance on submitting the budget and work plan will follow the release of this supplemental.**

**B. Required Forms (The following forms should be submitted to PGO by email with a copy to the appropriate DSLR Project Officer.**

- Form PHS 5161-1 is available from the CDC Procurement and Grants office at the following Internet address: <http://www.cdc.gov/od/pgo/forminfo.htm>
- Application budget preparation guidance is also available at: <http://www.cdc.gov/od/pgo/funding/budgetguide2004.htm>
- Forms SF-424 (Cover page) and SF-424B (Assurances) are available from the Office of Management and Budget: [http://www.whitehouse.gov/omb/grants/grants\\_forms.html](http://www.whitehouse.gov/omb/grants/grants_forms.html)
- Form SF-424A can also be obtained at the following Internet address: [http://www.whitehouse.gov/omb/grants/grants\\_forms.html](http://www.whitehouse.gov/omb/grants/grants_forms.html)
- Cover letter signed by Principal Investigator/Project Director of Public Health Preparedness Cooperative Agreement and representative of the business office.
- Detailed Budget and Justification, using the provided Excel spreadsheet under the “File Download” section of the MIS homepage.
- Detailed Work Plan using the blank MS Word template provided under the “File Download” section of the MIS homepage

**C. Technical Review:** Applications will be reviewed for technical acceptability by the Division of State and Local Readiness and HRSA BHPP Project Officers and other CDC subject matter experts to determine:

- the applicant’s current capability to perform the critical tasks
- that the operational plan clearly and adequately addresses the goals, tasks, and measures
- the extent to which the applicant clearly defines an evaluation plan that leads to continuous quality improvement of pandemic influenza response
- the extent to which the applicant presents a detailed budget with a line item justification and any other information to demonstrate that the request for assistance is consistent with the purpose and objectives of the cooperative agreement.

**D. Intergovernmental Review of Applications:** Applications are subject to Intergovernmental Review of Federal Programs, as governed by Executive Order (EO) 12372. This order sets up a system for State and local governmental

review of proposed federal assistance applications. Contact your State single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your State's process. Click on the following link to get the current SPOC list:

<http://www.whitehouse.gov/omb/grants/spoc.html>

#### **E. Technical Reporting Requirements For Supplemental Funding**

**Semi Annual Progress Reports** for the Budget Period must be submitted through the DSLR MIS. CDC has amended the requirements for technical reporting changing from quarterly to semiannual progress reports (see technical reporting requirements; VI Section E in 2006 PHEP CA). CDC will provide templates for these reports to assess program outcomes related to activities undertaken in the Budget Period. In addition, recipients may be required to submit information upon request based on changing threat status or national security priorities. Progress reports for activities undertaken, as well as special topics related to the goals and objectives are due on:

- **April 15, 2007**
- **November 30, 2007**

**Financial Status Reports (FSR): Due to separate accounting requirements please submit both a summary and an individual FSR addressing supplemental pandemic influenza activities. An original and two copies must be submitted in hard copy to CDC's PGO and are due on:**

- **May 30, 2007** A mid-year estimated FSR.
- **November 30, 2006** A final FSR is due 90 days after the end of the budget period.

**Please submit the hard copies of financial status reports (FSRs) to:**

Attn: Sharon Robertson  
 Grants Management Specialist—Regions 1, 2, 3, 4, 10  
 Acquisition and Assistance Branch VI  
 Procurement and Grants Office  
 Centers for Disease Control and Prevention (CDC)  
 2920 Brandywine Road  
 Atlanta, Georgia 30341-4146

### **Agency Contacts**

**DSLR Project Officers**—see Appendix 9 of the 2006 PHEP Cooperative Agreement

**For general questions, contact:**

Sharon Robertson

Grants Management Specialist—Regions 1, 2, 3, 4, 10  
Acquisition and Assistance Branch VI  
Procurement and Grants Office  
Centers for Disease Control and Prevention (CDC)  
2920 Brandywine Road  
Atlanta, Georgia 30341-4146  
Telephone: (770) 488-2748  
E-mail address: [sqr2@cdc.gov](mailto:sqr2@cdc.gov)

Angela Webb  
Grants Management Specialist—Regions 5, 6, 7, 8, 9  
Acquisition and Assistance Branch VI  
Procurement and Grants Office  
Centers for Disease Control and Prevention (CDC)  
2920 Brandywine Road  
Atlanta, Georgia 30341-4146  
Telephone: (770) 488-2784  
E-mail address: [aqw6@cdc.gov](mailto:aqw6@cdc.gov)



# Attachment A

## Performance Measures for FY 2006 Pandemic Influenza Emergency Supplemental Funding

| Measure 1: Medical Surge<br>Target Capability: Medical Surge. Use BioSense data to determine available beds that could be used for medical surge.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                      |                                                                                                                    |                                                                                                                                               |                                                                                                                                                                     |                                  |                                                                                                                                    |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|------------------------------------------------------------------------------------------------------------------------------------|
| CDC Preparedness Goal                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Proposed Measure                                                                                                                                                     | Jurisdictional Target                                                                                              | Definitions and Other Guidance                                                                                                                | Instructions                                                                                                                                                        | Jurisdictional Measurement Level | Data Collection and Submission Methods                                                                                             |
| CDC Goal 6: Control                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Percent of HRSA National Bioterrorism Hospital Preparedness Program (NBHPP) awardee hospitals that transmit hospital utilization data in near-real time to BioSense. | 90% of HRSA NBHPP awardee hospitals.                                                                               | Definitions:<br><u>Hospital utilization data</u> : BioSense Data Elements of Interest:<br>Includes number of beds available by facility unit. | <b>Numerator:</b> Number of HRSA NBHPP awardee hospitals that transmit hospital utilization data to BioSense.                                                       | State                            | Numerator data: DSLR retrieves data from CDC BioSense databases to determine which jurisdiction hospitals transmit to BioSense     |
| 6A: Target Capability: Medical Surge                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                      |                                                                                                                    |                                                                                                                                               | <b>Denominator:</b><br>Number of HRSA NBHPP awardee hospitals in the jurisdiction.<br><br>Near real-time: bed-count data is submitted at least once every 24 hours. |                                  | Denominator data: Pandemic Supplemental funding awardees declare to DSLR which hospitals in their jurisdiction are NBHPP awardees. |
| <ul style="list-style-type: none"> <li>Department of Homeland Security: Target Capabilities. Version 2.0 available at emergency responder password protected website: <a href="http://www.hhs.gov">www.hhs.gov</a></li> <li>Justification: CNA Corporation. Medical Surge Capacity and Capability: A Management System for Integrating Medical and Health Resources during Large-Scale Emergencies. Virginia, CNA. Under U. S. Department of Health and Human Services Contract # 233-03-0028. 2004. Page 8-6. Available at: <a href="http://www.cna.org/documents/mscc_aug2004.pdf">http://www.cna.org/documents/mscc_aug2004.pdf</a> Accessed June 9, 2006.</li> </ul> |                                                                                                                                                                      |                                                                                                                    |                                                                                                                                               |                                                                                                                                                                     |                                  |                                                                                                                                    |
| Measure 2: Seasonal Flu Clinic<br>Target Capability: Mass Prophylaxis. Use computer modeling to estimate patient throughput and compare to actual throughput during annual influenza vaccination clinic ("flu clinic").                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                      |                                                                                                                    |                                                                                                                                               |                                                                                                                                                                     |                                  |                                                                                                                                    |
| CDC Preparedness Goal                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Proposed Measure                                                                                                                                                     | Jurisdictional Target                                                                                              | Definitions and Other Guidance                                                                                                                | Instructions                                                                                                                                                        | Jurisdictional Measurement Level | Data Collection and Submission Methods                                                                                             |
| CDC Goal 6: Control                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Percent of estimated patient throughput actually achieved for each shift during mass vaccination clinic.                                                             | For each work shift: Meet or exceed estimated patient throughput for inputs entered into specified computer model. | <u>Specified computer model</u> : Use mass vaccination clinic operations model available at URL cited below.                                  | <b>Numerator:</b> # of persons vaccinated during each shift.<br><br><b>Denominator:</b> # of persons expected to be vaccinated during a                             | State and local                  | Data will be collected during real event seasonal flu clinics.                                                                     |
| 6C: Target Capability: Mass Prophylaxis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                      |                                                                                                                    |                                                                                                                                               |                                                                                                                                                                     |                                  | Clinic staff inputs will vary from shift to shift                                                                                  |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |  |                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|-----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><u>Shift:</u> To generate model estimates the number of staff working per shift is assumed constant throughout the shift. The duration of each shift is at the discretion of the public health agency (e.g., 8 hours, 12 hours, etc).</p> <p><u>Inputs entered:</u><br/>Parameters entered into the model to estimate throughput. For example: 200 clinic and administrative staff working in a flu clinic configured per the model are expected to vaccinate 4 patients per minute.</p> |  | <p>shift, according to model.</p> | <p>depending on the number of staff available to work the shift. As inputs vary, estimates generated by the model will differ.</p> <p>Note:<br/># observed vaccinated/<br/># expected to be vaccinated.</p> <p>Example:<br/>Shift #1:<br/># observed vaccinated is 2 patients per minute<br/># expected vaccinated per the model is 4 patients per minute.</p> <p><math>O/E = 2/4 = 1/2</math><br/>To get percent: <math>\frac{1}{2} \times 100 = 50\%</math> of estimate achieved</p> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|-----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

- Throughput estimates: Department of Homeland Security (DHS) Target Capabilities require capacity (throughput) estimates for determining burden of work to manage standardized planning scenarios.
- Specified mass vaccinations clinic operations model: Model is funded by CDC and developed jointly by Montgomery County, Maryland, Advanced Practice Center for Public Health Emergency Preparedness and Response and The Computer Integrated Manufacturing Laboratory of the Institute for Systems Research at the University of Maryland. Model available at <http://www.isr.umd.edu/Labs/CIM/projects/clinic/> Accessed June 11, 2006.

|                                                                                                                                            |                  |                       |                                |                                        |
|--------------------------------------------------------------------------------------------------------------------------------------------|------------------|-----------------------|--------------------------------|----------------------------------------|
| Measure 3: Seasonal Flu Clinic.                                                                                                            |                  |                       |                                |                                        |
| Target Capability: Mass Prophylaxis. AGE AND RISK GROUPS – INFLUENZA VACCINATION. Exceed the influenza vaccination target coverage levels. |                  |                       |                                |                                        |
| CDC Preparedness Goal                                                                                                                      | Proposed Measure | Jurisdictional Target | Definitions and Other Guidance | Instructions                           |
|                                                                                                                                            |                  |                       |                                |                                        |
|                                                                                                                                            |                  |                       |                                | Jurisdictional Measurement Level       |
|                                                                                                                                            |                  |                       |                                | Data Collection and Submission Methods |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                    |                                                                                                                        |                                                                                                                                                                                                                         |                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| CDC Goal 6:<br>Control                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Influenza vaccination coverage levels for each age and risk group. | Better than the best: Jurisdiction exceeds the highest coverage level reported in the most recently published dataset. | DSLRL retrieves data from CDC databases                                                                                                                                                                                 |                     |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 6C:<br>Target Capability:<br>Mass Prophylaxis                      | “Better than the best” is borrowed from HP 2010, which employs the concept as a target-setting method.                 | Awardees’ progress toward targets is assessed using the latest survey vaccination rates available for the DSLRL reporting period. Publication of survey results can lag behind current reporting period a year or more. |                     |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                    | <b>Target source:</b>                                                                                                  | <b>Target tracked by:</b>                                                                                                                                                                                               |                     |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | • > or = 65 yr                                                     | 90%                                                                                                                    | HP 2010                                                                                                                                                                                                                 | BRFSS State         |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | • 18-64 yr with high-risk conditions                               | 60%                                                                                                                    | HP 2010                                                                                                                                                                                                                 | BRFSS State         |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | • Health-care workers with patient contact                         | Better than the best                                                                                                   | BRFSS (In vaccine shortage season: Years 2004 – 05, the national level estimate was 36%)                                                                                                                                | BRFSS State         |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | • 18-64 yr – Non-priority group                                    | Better than the best                                                                                                   | BRFSS (In non-shortage season: Years 2003-04, the national estimate was 24%)                                                                                                                                            | BRFSS State         |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | • 6-23 months                                                      | Better than the best                                                                                                   | NIS                                                                                                                                                                                                                     | NIS State and Local |
| <ul style="list-style-type: none"> <li>MMWR: <i>Estimated Influenza Vaccination Coverage Among Adults and Children –United States, September 1, 2004–January 31, 2005</i>. MMWR. April 1, 2005 54 (12); 304-307. Available at: <a href="http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5412a3.htm">http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5412a3.htm</a> Accessed: June 9, 2006.</li> <li>MMWR: <i>Prevention and Control of Influenza. Recommendations of the Advisory Committee on Immunization Practices (ACIP)</i>. June 28, 2006 /55 (Early Release); 1-41. Available at: <a href="http://www.cdc.gov/mmwr/preview/mmwrhtml/rr55e628a1.htm">http://www.cdc.gov/mmwr/preview/mmwrhtml/rr55e628a1.htm</a> Accessed July 3, 2006.</li> <li>Influenza Vaccination Coverage Levels. Available at: <a href="http://www.cdc.gov/flu/professionals/vaccination/coveragelevels.htm">http://www.cdc.gov/flu/professionals/vaccination/coveragelevels.htm</a> Accessed July 3, 2006.</li> <li>BRFSS is Behavioral Risk Factor Surveillance System. Available at: <a href="http://www.cdc.gov/BRFSS/">http://www.cdc.gov/BRFSS/</a> Accessed July, 3 2006.</li> <li>NIS is National Immunization Survey. Available at: <a href="http://www.cdc.gov/nis/">http://www.cdc.gov/nis/</a> Accessed July 3, 2006.</li> <li>HP 2010 is Healthy People 2010. Target setting methods available at: <a href="http://www.healthypeople.gov/Document/HTML/tracking/THP_PartA.htm#TargetSetting">http://www.healthypeople.gov/Document/HTML/tracking/THP_PartA.htm#TargetSetting</a> Accessed July 3, 2006.</li> </ul> |                                                                    |                                                                                                                        |                                                                                                                                                                                                                         |                     |

Measure 4: Non-Pharmacological Public Health Interventions: Social Distancing.  
Target Capability: Planning

| CDC Preparedness Goal           | Proposed Measure                                                                                                  | Jurisdictional Target                                                        | Definitions and Other Guidance                                                                                                                                                                                                                                              | Instructions | Jurisdictional Measurement Level | Data Collection and Submission Methods |
|---------------------------------|-------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|----------------------------------|----------------------------------------|
| CDC Goal 1: Prevent             | Public health officials recommend school closure when pandemic influenza case counts reach pre-determined levels. | Jurisdictions pre-determine case count levels that “trigger” school closure. | Jurisdictions are expected to be hyper-vigilant about the introduction of pandemic influenza in their communities. Pre-event, jurisdictions determine how many cases infected with H5, or another novel subtype, of influenza will prompt them to recommend school closure. |              | State and local                  | Drill or exercise                      |
| 1A: Target Capability: Planning |                                                                                                                   |                                                                              | <p>Pandemic influenza cases: When disease prevalence is low, laboratory testing should be confirmatory (as opposed to presumptive).</p>                                                                                                                                     |              |                                  |                                        |

- School District (K-12) Pandemic Influenza Planning Checklist. Available at: <http://www.pandemicflu.gov/plan/schoolchecklist.html> Accessed June 18, 2006.
- Heymann A, Chodick G, Reichman B, Kokia, E, Laufer J, *Influence of school closure on the incidence of viral respiratory diseases among children and on health care utilization*. *Pediatr Infect Dis J*. 2004 Jul; 23 (7): 675-7.
- HHS Pandemic Influenza Plan, US Dept of Health and Human Services. November 2005. Available at: [www.pandflu.gov](http://www.pandflu.gov) Accessed June 21, 2006.

## Measure 5: Isolation

Target Capability: Isolation and Quarantine. During drills and exercises make timely decisions to seek court order for isolation or release detained patient.

| Goal                                            | Proposed Measure                                                                                | Jurisdictional Target | Guidance                                                                                                                                                                                                                                                                                      | Instructions                                                                                                                                                                                                                                                                                               | Jurisdictional Measurement Level | Data Collection and Submission Methods                          |
|-------------------------------------------------|-------------------------------------------------------------------------------------------------|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|-----------------------------------------------------------------|
| CDC Goal 6: Control                             | Time an individual (s) is detained for medical evaluation while determining need for isolation. | < 12 hours            | Detain: Restrict movement by preventing individual from leaving the designated area while he/she is medically evaluated.                                                                                                                                                                      | <b>Date and Start time:</b><br>Date and time public health authority first detains individual(s).                                                                                                                                                                                                          | State and local                  | Data collected for each individual detained for evaluation.     |
| 6B: Target Capability: Isolation and Quarantine |                                                                                                 |                       | <p>This measure includes time to obtain presumptive laboratory results.</p> <p>This measure <b>does not</b> include time to get a judge or magistrate to sign the order, which can take considerably longer.</p> <p>This measure also <b>does not</b> include evaluations for quarantine.</p> | <b>Date and Stop time:</b><br>Any one of the following: <ul style="list-style-type: none"> <li>Date and time on petition for court order.</li> <li>Date and time patient is placed under voluntary isolation.</li> <li>Date and time patient is released after deemed not in need of isolation.</li> </ul> |                                  | In the case of mass isolation data is collected for the cohort. |

## Measure 6: PHIN Compliance

Target Capability: Communications. PHIN compliance enables information technology systems to support detection and containment of pandemic influenza across all Target Capabilities.

| CDC Preparedness Goal                 | Proposed Measure                                                                                                                                                                                                                                                                                      | Jurisdictional Target                                                 | Definitions and Other Guidance                                                                                                                                                                              | Instructions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Jurisdictional Measurement Level | Data Collection and Submission Methods                                                                                                                                                                         |
|---------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| CDC Goal 4: Detect and Report         | For each PHIN Functional Area, the percent of critical functional requirements that have been achieved based on either the Functional Self Assessment Tool or the PHIN certification process. The Functional Areas are:                                                                               | 100% of the critical functional requirements for each Functional Area | <b>Note:</b> For each Functional Area cite the assessment method used to determine achievement:<br>Self Assessment (Self-Assessment Tool )<br>OR<br>(Independent Assessment)<br>PHIN Certification process. | <b>Example:</b><br>1)<br>Connecting Laboratory Systems has 10 critical functional requirements. The recipient using the Functional Self Assessment tool has achieved 7 of the critical functional requirements. The Connecting Laboratory Systems score is 7/10 or 70% by Functional Self Assessment Tool.<br><br>2)<br>Countermeasure/Response Administration has 5 critical functional requirements. The recipient has achieved all 5 critical functional requirements based on the PHIN Certification process. The Countermeasure/Response Administration score is 5/5 or 100% by PHIN Certification process. | State and local                  | Recipient's plan for addressing identified gaps AND either the PHIN Certification Status Letter for each Functional Area or the Summary page from the Functional Self Assessment Tool for each Functional Area |
| 4A: Target Capability: Communications | <ul style="list-style-type: none"> <li>Connecting Laboratory Systems</li> <li>Countermeasure/Response Administration</li> <li>Cross-functional Components</li> <li>Early Event Detection</li> <li>Outbreak Management</li> <li>Partner Communications and Alerting Functional Requirements</li> </ul> |                                                                       |                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                  |                                                                                                                                                                                                                |

- Public Health Information Network (PHIN) Certification: Standards, Self-Assessment Tools and Certification process available at: <http://www.cdc.gov/phn/certification/index.html> Accessed November 16, 2005

## Attachment B

### List of Critical Tasks Organized by Pandemic Flu Goals and Target Capabilities

CDC considers the Critical Tasks below to be central to a comprehensive pandemic influenza preparedness strategy. Given continued funding, CDC expects the following tasks to be implemented, monitored and evaluated on an on-going basis.

#### **Pandemic Influenza Preparedness Goal 1: PREVENT**

Increase the use and development of clinical, non-pharmaceutical, and risk communications interventions known to minimize the spread of influenza.

#### **1A Target Capability: Planning** (links to HHS State and Local Pandemic Influenza Planning Checklist, Community Preparedness, Leadership and Networking)

##### **Critical Task(s):**

1. Develop, exercise and improve operational plans for pandemic influenza at the state and local level. Plans must:
  - a) be compliant with National Incident Management System and include Incident Command System (ICS)
  - b) delineate accountability and responsibility for key local authorities and stakeholders engaged in planning and executing specific components of the operational plan (e.g., identification, isolation, quarantine, movement restriction, healthcare services, emergency care, mutual aid and school closure)
  - c) link plan activities to WHO Pandemic Influenza Phases <sup>6</sup>
  - d) identify which plan activities will occur at state, local, or coordinated level
  - e) define State role in providing guidance and assistance to the local, tribal and regional levels
  - f) address integration of state, local, tribal, territorial, and regional plans across jurisdictional boundaries
  - g) address the provision of psychosocial support services for the community, including parents and their families, and those affected by community containment procedures
  - h) be sufficiently flexible to adapt to the magnitude and severity of the pandemic and to available resources
  - i) identify how public health, hospitals and healthcare systems will establish systems for healthcare facility level infection control while allowing necessary personnel access to the facility
  - j) Address the needs of vulnerable/special populations <sup>7</sup>

---

<sup>6</sup> See World Health Organization (WHO) Pandemic Influenza Phases at [http://www.who.int/csr/resources/publications/influenza/GIP\\_2005\\_5Eweb.pdf](http://www.who.int/csr/resources/publications/influenza/GIP_2005_5Eweb.pdf)



2. Formalize agreements that address communication, mutual aid, and other cross-jurisdictional needs with neighboring domestic and/or international jurisdictions sharing an international border with Canada or Mexico (e.g., city-state-tribal collaboration arrangements or city-state-province/state collaboration arrangements)
3. Assess and map local community; identify and build social networks; and develop community outreach information networks, pre-event, to
  - a) define, locate and reach special, at-risk and vulnerable populations and
  - b) maximize capacity to effectively disseminate public information during a pandemic.
4. Clarify and communicate to all stakeholders the process for requesting, coordinating, and approving requests for resources to state and federal agencies
5. Ensure that legal authorities for executing the operational plan, especially those relevant to case identification, isolation, quarantine, movement restriction, healthcare services, emergency care, and mutual aid, are transparent to all stakeholders <sup>8</sup>
6. Develop and document schemes to activate non-pharmacological interventions, including home isolation of patients and quarantine of household contacts, social distancing measures such as closure of schools and workplaces, reduced public transport, cancellation of mass gatherings and public education on hygiene measures such as hand and respiratory hygiene. The scheme should clearly outline how and when decisions are made to implement the interventions.
7. Identify and communicate to all stakeholders the authority responsible for declaring a public health emergency at the state, local and tribal levels and for officially activating the pandemic influenza response plan
8. Identify State, local and tribal law enforcement personnel who will maintain public order and help implement control measures
9. Exercise operational plan in cooperation with animal health sectors (including but not limited to industry, veterinary diagnostic laboratories, state departments of agriculture), to prevent, detect and respond to reports of disease in animals as a early warning of threat to human health including:
  - a) education of and risk communication to the poultry owning public, poultry farmers and vendors, especially small operations
  - b) a plan for surveillance in birds
  - c) disease reporting and data sharing
  - d) triggers for action to contain disease within the animal sector
  - e) triggers to perform heightened surveillance to detect human illness
10. Train to and exercise the operational elements of the jurisdictional plan including plan activation, incident command, integration with partner agencies; integration with and assistance to hospitals and healthcare systems particularly regarding surge capacity, assisting persons with special needs, coordination with schools

---

<sup>7</sup> See the Public Health Workbook to Define, Locate and Reach Special, Vulnerable and At-Risk Populations in an Emergency at [www.bt.cdc.gov/workbook](http://www.bt.cdc.gov/workbook)

<sup>8</sup> See Appendix E, Legal Authorities of DHHS Pandemic Influenza Plan, <http://www.hhs.gov/pandemicflu/plan/pdf/part2.pdf>

11. Conduct at least one exercise per year jointly with HHS and DHS funded pandemic influenza responders through exercises, drills, tabletop exercises, etc.
12. Assign responsibilities and resources to complete, update and execute the plan. Assure that the plan includes timelines and Outcomes to be achieved as well as back-up systems for each part of the plan

**Measure(s):**

1. Public health agency has primary and secondary staff identified for core functional roles delineated in the Incident Command System (ICS) for public health
2. Public health officials recommend school closure when pandemic influenza case counts reach pre-determined levels.

### **Pandemic Influenza Preparedness Goal 3: DETECT AND REPORT**

Decrease the time needed to detect and report an influenza outbreak with pandemic potential.

**3A Target Capability: Epidemiological Surveillance and Investigation** (links to HHS State and Local Pandemic Influenza Planning Checklist, Surveillance)

**Critical Task(s):**

1. Recruit and maintain a group of healthcare providers that report influenza-like illness (ILI) regularly, year-round, to the influenza sentinel provider surveillance network
2. Develop the ability to rapidly provide healthcare providers, clinics, and hospitals with updated information on case definitions and sample collection requests and protocols
3. Establish a system for healthcare providers to contact public health authorities about suspect cases or outbreaks
4. Develop an electronic system for rapid reporting of deaths and contributing causes of death (i.e. pneumonia and influenza-related) occurring in the state
5. Improve capacity for rapid identification of unusual influenza strains by working with federal partners to enhance laboratory-based monitoring of seasonal influenza subtypes
6. Ensure that tribal entities such as local Service Units, tribal health facilities and Area IHS review mechanism for influenza case reporting and identify local surveillance coordinators, thereby assuring linkage of local surveillance activities with federal, state and local systems
7. Inventory and maintain tribal and IHS supplies of influenza rapid diagnostic tests
8. Coordinate protocols for influenza testing with tribal entities and establish means of transportation for respiratory specimens to State public health laboratories when necessary
9. Develop protocols to enhance surveillance activities for early detection of influenza-like illness (ILI) among patients and health care workers at Tribal/IHS facilities.

**Measure(s):**

1. Time for state public health agency to notify local public health agency, or local to notify state, following receipt of a call about an event that may be of urgent public health consequence

**3B Target Capability: Public Health Laboratory Testing** (links to HHS State and Local Pandemic Influenza Planning Checklist, Public Health and Clinical Laboratories)

**Critical Task(s):**

1. Maintain the ability to test for influenza viruses year-round
2. Perform Polymerase Chain Reaction (PCR) testing for rapid detection and subtyping of influenza viruses
3. Electronically exchange specimen-level data among clinical laboratories, the state public health lab, and CDC
4. Institute surveillance for influenza-like illness (ILI) among laboratory personnel working with novel influenza viruses
5. Develop and exercise an operational plan to augment the capacity of public health and clinical laboratories to meet the needs of the jurisdiction during an influenza pandemic
6. Assess all public health and clinical laboratory influenza diagnostic testing proficiency and adherence to biosafety containment and biomonitoring protocols at least annually
7. Test the knowledge and competency of frontline clinicians and laboratory personnel with regard to:
  - a) Protocols for safe specimen collection and testing
  - b) How and to whom a potential case of novel influenza should be reported
  - c) Mechanism for submitting specimens to referral laboratories
8. Determine how hospitals and health care systems will use systems and communications tools to report information to public health and response partners with an emphasis on regional hospital coordination

**Measure(s)**

1. Time from presumptive identification to confirmatory identification of select agents by Laboratory Response Network (LRN) reference lab
2. Time to have a knowledgeable LRN reference laboratorian answer a call during non-business hours

**Pandemic Influenza Preparedness Goal 4: DETECT AND REPORT**

Improve the timeliness and accuracy of communications regarding the threat posed by an influenza outbreak with pandemic.

**4A Target Capability: Communications** (links to HHS State and Local Pandemic Influenza Planning Checklist, Public Health Communications.)

1. Support exchange of essential information before and during an influenza pandemic. Coordinate procurement and placement of technology communication systems that, based on a gap analysis of requirements versus existing capabilities, are compliant with PHIN Preparedness Functional Area *Partner Communication and Alerting*.
2. Have or have access to interoperable information systems that support the initial identification and that provide situational awareness of possible pandemic influenza

outbreak in compliance with PHIN Preparedness Functional Area *Early Event Detection*.

- a) Receive, triage and send case or suspect case disease reports 24/7/365.
  - b) Receive health related data from multiple data sources to monitor, quantify and localize aberrations to normal data patterns (e.g., veterinary systems, school absenteeism reports, hospital utilization data, nurse call lines, over-the-counter drug sales, poison control center reports).
3. Have or have access to interoperable information systems to capture and manage data associated with the investigation and containment of an outbreak (e.g., pandemic influenza) or public health emergency in compliance with PHIN Preparedness Functional Area *Outbreak Management*.
4. Have or have access to interoperable information systems for electronic exchange of laboratory related information with public health partners (e.g. to support laboratory surveillance and electronic reporting in a pandemic) in compliance with PHIN Preparedness Functional Area *Connecting Laboratory Systems*.
5. Have or have access to interoperable information systems that comply with PHIN Preparedness Functional Area *Countermeasure and Response Administration* to allocate, manage and track measures taken to contain or provide protection against an actual or possible outbreak or event.
  - a) Deliver prophylaxis and manage isolation and quarantine.
  - b) Monitor adverse events and follow-up of patients.
6. Have or have access to interoperable information systems that span PHIN functional areas by adhering to standards and specifications for public health system and data architecture requirements (e.g., secure message exchange, terminology standards and public health directory) in compliance with PHIN Preparedness Functional Area *Cross Functional Components*.
7. Develop plans to address gaps in achieving PHIN certification.

**Measure(s):**

1. For each PHIN Functional Area, the percent of critical functional requirements that have been achieved based on either the Functional Self Assessment Tool or the PHIN certification process. The Functional Areas are:
  - Connecting Laboratory Systems
  - Countermeasure/ Response Administration
  - Cross-functional Components
  - Early Event Detection
  - Outbreak Management
  - Partner Communications and Alerting Functional Requirements

**Pandemic Influenza Preparedness Goal 5: INVESTIGATE**

Decrease the time to understand modes of transmission, risk groups and risk factors, and appropriate interventions.

**5A Target Capability: Epidemiological Surveillance and Investigation** (links to HHS State and Local Pandemic Influenza Planning Checklist, Surveillance)

**Critical Task(s):**

1. Conduct year-round surveillance for seasonal influenza (e.g. virologic, outpatient visits, hospitalization, and mortality) preferably through the use of electronic reporting
2. Assure capacity to implement enhanced surveillance once a pandemic is detected, to ensure recognition of the first cases of pandemic virus infection in time to initiate appropriate containment protocols
3. Link animal and human health surveillance systems and routinely share information
4. Develop systems to obtain and track numbers and rates of these Outcomes daily during an influenza pandemic on:
  - a) the numbers of newly hospitalized persons with influenza or pneumonia
  - b) the numbers of newly isolated and quarantined persons, and
  - c) hospitals with pandemic influenza cases
  - d) the number of pneumonia or influenza-associated deaths

**Measure(s):**

1. Time for State/territory public health agency to notify local public health agency, or local to notify State, following receipt of a call about an event that may be of urgent public health consequence

**Pandemic Influenza Preparedness Goal 6: CONTROL**

Decrease the time needed to implement rapid outbreak response actions and provide other countermeasures, including personnel, risk communications, and health interventions and guidance to those at risk of pandemic influenza

**6A Target Capability: Medical Surge** (link to HHS State and Local Pandemic Influenza Planning Checklist, Healthcare and Public Health Partners)

**Critical Task(s):**

1. Before March 31, 2007, coordinate with the HRSA Bioterrorism coordinator to detail the gaps identified in the HRSA NBHPP program Pandemic Influenza Scenario and a plan for how funds from this Supplement would be used to augment funding provided by the HRSA NBHPP program.
  - a) In concert with public health partners, ensure that healthcare entities (primary care, community health centers, rural health programs, and hospitals) are a key component in the exercising of state, local and tribal plans that address:
    - i. maintenance of essential hospital support functions
    - ii. severe shortages of health care workers

- iii. adequate personnel and staffing needs based on CDC's FluSurge software
  - iv. use of the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) to obtain volunteer health care workers
  - v. ensuring real-time situational awareness of patient visits, hospital bed and intensive care needs, medical supply needs and medical staffing needs.
  - vi. the purchase and storage of beds, equipment, supplies, pharmaceuticals needed to treat influenza patients
  - vii. mass fatalities and maximizing morgue capabilities
- b) Exercise communication systems, plans and procedures to ensure that hospitals, health care systems and public health inform the community about the operating status of hospitals and the triggers for sending a person to the hospital
  - c) Exercise vaccination and prophylaxis plans to cover healthcare staff and patients
  - d) Exercise triage and admission plans that would serve to minimize stress on the hospital system and maintain control of the situation
  - e) Hospitals and health care systems in conjunction with public health partners identify the location, set-up, staffing and operation of alternate care sites during a pandemic. Focus for sites should be within metropolitan areas with plans that can support the sub-state region in which the metropolitan area is contained. States should make firm logistical arrangements for the selection, set-up (beds, medical supplies and equipment, personal protective equipment, pharmaceuticals, etc) staffing and operation (to include food, fuel and water) of alternate care facilities to meet the needs during the peak period of a pandemic wave (2-3 weeks).
  - f) Identify how public health, hospitals and healthcare systems will establish systems for healthcare facility level infection control while allowing necessary personnel access to the facility

**Measure(s):**

- 1. Percent of HRSA National Bioterrorism Hospital Preparedness Program (NBHPP) awardee hospitals that transmit hospital utilization data in near-real time to BioSense.

**6B. Target Capability: Isolation and Quarantine** (Link to HHS State and Local Pandemic Influenza Planning Checklist, Infection Control and Clinical Guidelines, and Community Disease Control and Prevention)

**Critical Task(s):**

- 1. Develop and exercise an operational plan for community mitigation of pandemic influenza using non-pharmacological, including home isolation of patients and quarantine of household contacts, social distancing measures such as closure of schools and workplaces, reduced public transport, and cancellation of mass



- gatherings, and public education on hygiene measures such as hand and respiratory hygiene.
2. Conduct multiple municipal or regional tabletop exercises regarding the decision-processes associated with school closure and the use of other non-pharmacologic interventions.
  3. Develop and exercise a plan to communicate to healthcare providers about infection control guidelines and for communication about containment measures at the State, local and tribal level
  4. Exercise and improve the ability to implement infection control guidelines and public health measures at the State, local and tribal levels
  5. Disseminate information from public health sources on:
    - a) routine infection control (e.g., hand hygiene, cough/sneeze etiquette)
    - b) pandemic influenza fundamentals (e.g., signs and symptoms of influenza, modes of transmission)
    - c) personal and family protection and response strategies (e.g., guidance for the at-home care of ill students and family members)
  6. Develop and exercise an operational plan for isolation and quarantine that delineates the following:
    - a) the criteria for isolation and quarantine
    - b) the procedures and legal authorities for implementing and enforcing these containment measures, and
    - c) the methods that will be used to support, service, and monitor those affected by these containment measures in healthcare facilities, other residential facilities, homes, community facilities, and other settings
  7. Develop and exercise an operational plan to implement various levels of movement restrictions within, to, and from the jurisdiction
  8. Inform citizens in advance what community mitigation measures may be used in the jurisdiction (e.g. tabletop exercises)
  9. Develop and exercise an operational plan for implementing social distancing measures in a jurisdiction that addresses school and workplace closures and cancellation of public gatherings
  10. Implementation in sub-populations where non-pharmacological interventions may pose particular challenges
  11. Providing support and services to help counteract the secondary impact of such measures
  12. monitoring compliance with non-pharmacological interventions including tracking persons in quarantine

#### **Measure(s)**

1. The time to issue an isolation or quarantine order
2. Time an individual is retained for medical evaluation while determining need for isolation



3. Public health officials recommend school closure when pandemic influenza case counts reach pre-determined levels.

**6C Target Capability: Mass Prophylaxis** (link to HHS State and Local Pandemic Influenza Planning Checklist, Vaccine Distribution and Use, and Antiviral Drug Distribution and Use)

**Critical Task(s):**

1. Describe the receipt, distribution, storage, security, monitoring and administration of pandemic influenza vaccines including plans for limited vaccine availability and prioritization of population groups. Take into account potential for administration of **vaccines subject to** Investigational New Drug (IND) or Emergency Use Authorization (EUA)
2. Collaborate in mass prophylaxis planning and exercising with community-wide partners, bordering jurisdictions, IHS and tribal nations
3. Maintain PHIN compliant information systems for tracking vaccine distribution and administration

**Measure(s):**

1. Adequacy of State and local plans to receive and dispense medical countermeasures as demonstrated through assessment by the Strategic National Stockpile/Cities Readiness Initiative (CRI)
2. Percent of estimated patient throughput actually achieved for each shift during mass vaccination clinic
3. Influenza vaccination coverage levels reported by BRFSS for each age and risk group.

**6D Target Capability: Emergency Public Information and Warning** (links to HHS State and Local Pandemic Influenza Planning Checklist, Public Health Communications.)

**Critical Task(s):**

1. Exercise communication plans with an emphasis on:
  - a) coordination with response partners and tribal nations
  - b) rapid provision of public health risk information and recommendations
  - c) addressing stigmatization, rumors and misperceptions in real time
  - d) surge capacity for public information, media operations and spokespersons
  - e) procedures to secure resources to activate the public information and media operation during a public health emergency around the clock if needed for a minimum of 10 days
2. Prepare supporting materials for public health issues that are unique to an influenza pandemic such as issues of isolation, social distancing, and public health law
3. Establish a contact list of additional spokespersons and persons outside the state health department who can be available as subject matter experts on pandemic health

issues to respond as surge capacity to meet demands for speakers or interviewees from the media, civic organizations and others

4. Identify additional and nontraditional vehicles of information dissemination to the public, partners and stakeholders

**Measure(s):**

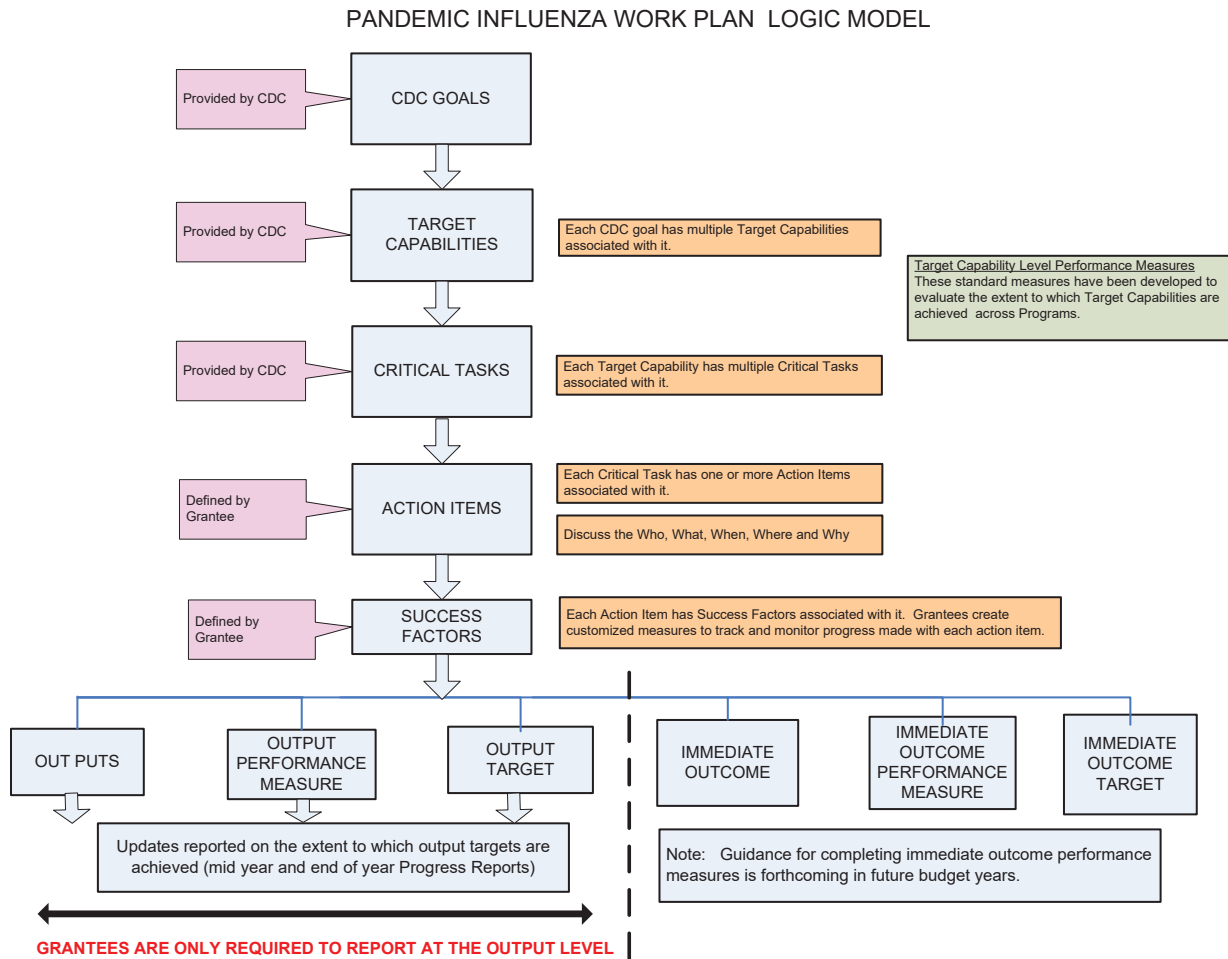
1. Time to issue critical health message to the public about an event that may be of urgent public health consequence

**6F Target Capability: Community Preparedness and Participation** (link HHS State and Local Pandemic Influenza Planning Checklist, Workforce Support: Psychosocial Considerations and Information Needs)

**Critical Task(s):**

1. Develop and exercise a continuity of operations plan for essential department services that includes:
  - a) contingency planning for increasing public health workforce in response to absenteeism among health department staff and stakeholder groups that have key responsibilities under a community's response plan
  - b) ensuring availability of psychosocial support services (including educational and training materials) for employees who participate in or provide support for the response to public health emergencies such as influenza pandemics

## Attachment C



## 2006 Pandemic Influenza Work Plan Guidance

### Attachment D

#### Work Plan Template for Pandemic Flu Guidance

**GRANTEES SHOULD FILL OUT A SEPARATE TEMPLATE FOR EACH ACTION ITEM**

|                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>CDC Goal:</b> Each Goal can have multiple Target Capabilities associated with it.                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                             |
| <ul style="list-style-type: none"> <li>CDC goals form the framework for public health activities surrounding preparedness</li> </ul>                                                                                                                                                                                            |                                                                                                                                                                                                                                             |
| <b>Target Capability:</b> Each Target Capability can have multiple Critical Tasks associated with it.                                                                                                                                                                                                                           |                                                                                                                                                                                                                                             |
| <ul style="list-style-type: none"> <li>Capabilities are combinations of people, equipment, and supplies which, through proper planning, equipping, training, organizing, and exercising, can perform critical tasks at expected levels of proficiency to achieve desired Outcomes in response to national disasters.</li> </ul> |                                                                                                                                                                                                                                             |
| <b>Associated CDC Performance Measure:</b> Indicate if this Target Capability relates to a CDC Performance Measure (Attachment A).                                                                                                                                                                                              |                                                                                                                                                                                                                                             |
| <ul style="list-style-type: none"> <li>Performance measure are leading indicators that allow a national snapshot to show how preparedness and response activities and their associated resources aid in making a public health system that responds more quickly and comprehensively in a public health emergency.</li> </ul>   |                                                                                                                                                                                                                                             |
| <b>Critical Task:</b> Each Critical Task can have multiple Action Items associated with it.                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                             |
| <ul style="list-style-type: none"> <li>Tasks deemed critical by science and expert opinion for each Capability to execute its mission.</li> </ul>                                                                                                                                                                               |                                                                                                                                                                                                                                             |
| <b>Action Item:</b> The program efforts conducted to achieve the critical tasks that result in the creation of a product or service.                                                                                                                                                                                            |                                                                                                                                                                                                                                             |
| <b>Description</b>                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                             |
| What                                                                                                                                                                                                                                                                                                                            | Purpose of the Action Item<br>What is the problem, or what is the opportunity, to be addressed by this Action Item?                                                                                                                         |
| Who                                                                                                                                                                                                                                                                                                                             | Target audience<br>What sectors are you trying to change or influence? (list all that apply):                                                                                                                                               |
|                                                                                                                                                                                                                                                                                                                                 | Stakeholders critical to success of the project<br>Who is responsible for the Outputs<br>Recipient and Agents of Change from above                                                                                                          |
| When                                                                                                                                                                                                                                                                                                                            | Time period of project<br>From mm/yyyy to mm/yyyy (maximum of 12 months)                                                                                                                                                                    |
| Where (addresses reach)                                                                                                                                                                                                                                                                                                         | Venue, location, etc.<br>Venue – Where interventions occur<br>Location – Geographic (list all that apply from the following): neighborhood/community, urban, rural, suburban, county, region/district, statewide                            |
| Why                                                                                                                                                                                                                                                                                                                             | Rationale<br>What evidence do you have to support the proposed intervention/course of action/Outcome for this Action Item? (Use experience if no data available)<br>What is the capacity of the recipient to deal this problem/opportunity? |

|                                                                 |                                                                                                        |                                                                                                                                                                                                                         |
|-----------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                 |                                                                                                        | Why does this Action Item deserve the recipient's attention now?<br>(Concisely summarize the above information.)                                                                                                        |
| <b>Success Factors for Action Item</b>                          |                                                                                                        |                                                                                                                                                                                                                         |
| Outputs                                                         | What does this action item produce?                                                                    | Direct products or services produced by the action item that lead to the intended Immediate Outcomes.                                                                                                                   |
| Output Performance Measure                                      | Measures the quantity or quality of the Output.                                                        | Output Performance Measures are indicators used to gauge the Quantity (i.e. How much was produced) and/or the Quality (How well an Output is produced/delivered) of the Output produced as a result of the Action Item. |
| Output Target                                                   | Pre established value (number or percentage) that the program is trying to reach at the Output level.  | Targets are the quantifiable or otherwise measurable characteristics (e.g. number or percentage) that tell how well a program must accomplish a performance measure.                                                    |
| Immediate Outcome*                                              | Describe the intended result that will occur from one or more Outputs?                                 | Intended result that will occur from one or more Outputs.                                                                                                                                                               |
| Immediate Outcome Performance Measure*                          | Measures the effectiveness of the Immediate Outcome.                                                   | Immediate Outcome Performance Measures are indicators that gauge how successful Outputs are at producing Immediate Outcomes.                                                                                            |
| Outcome Target*                                                 | Pre established value (number or percentage) that the program is trying to reach at the Outcome level. | Targets are quantifiable or otherwise measurable characteristics (e.g. number or percentage) that tell how well a program must accomplish a performance measure.                                                        |
| <b>Progress Report- To be Reported Mid Year and End of Year</b> |                                                                                                        |                                                                                                                                                                                                                         |
| Progress Report- Outputs                                        | Provide updates (quantifiable) regarding the achievement of                                            | Extent to which the target Outputs have been achieved. Reported in the form a quantifiable or measurable characteristic.                                                                                                |

|                              |                                              |                                                                                   |
|------------------------------|----------------------------------------------|-----------------------------------------------------------------------------------|
|                              | Output performance measures                  |                                                                                   |
| Progress Report-<br>Barriers | Barriers/problems faced in achieving Outputs | Briefly explain if any barriers were encountered in achieving the target Outputs. |

**Note: \*Grantees only need to report on Outputs, Output Performance Measures and Output Targets. They are not required to report Immediate Outcomes, Outcome Performance Measures and Outcome Targets.**

## Examples in the use of the Work Plan Template

|                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Example 1</b>                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>CDC Goal: Pandemic Influenza Preparedness Goal 6: Control</b>                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Target Capability: Mass Prophylaxis</b>                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>CDC Performance Measure: Measure 2, Seasonal Flu Clinic: Percent of estimated patient throughput actually achieved for each shift during mass vaccination clinic.</b>                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Critical Task: Describe the receipt, distribution, storage, security, monitoring and administration of pandemic influenza vaccines including plans for limited vaccine availability and prioritization of population groups.</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Name of Action Item: Identification of vaccination clinic locations (when public health is responsible for vaccination).                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| What                                                                                                                                                                                                                                | Purpose of the Action Item<br>Identifying and securing seasonal influenza vaccination clinic sites to exercise mass prophylaxis capabilities, including points of dispensing (PODs).                                                                                                                                                                                                                                                                              |
| Who                                                                                                                                                                                                                                 | Target audience<br>Utilizing current Advisory Committee on immunization practices guidelines for distribution/delivery of seasonal influenza vaccines, target audiences will be identified.<br>State health departments, local health jurisdictions, clinic volunteers, security/law enforcement, media, local politicians, state homeland security agency, health care sector and other partners selected from the Pandemic Influenza Planning Committee Roster. |
|                                                                                                                                                                                                                                     | Who is responsible for the Outputs<br>Local and State Public Health departments                                                                                                                                                                                                                                                                                                                                                                                   |
| When                                                                                                                                                                                                                                | Time period of project<br>From late September 2006 thru April 2007                                                                                                                                                                                                                                                                                                                                                                                                |
| Where (addresses reach)                                                                                                                                                                                                             | Venue, location, etc.<br>Sites in three high density and two rural local public health jurisdictions                                                                                                                                                                                                                                                                                                                                                              |
| Why                                                                                                                                                                                                                                 | Rationale<br>To test capabilities to deliver vaccines to the general population in a manner consistent with mass vaccination including points of dispensing (PODS)                                                                                                                                                                                                                                                                                                |
| <b>Success Factors</b>                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Outputs</b>                                                                                                                                                                                                                      | A list of local clinics located in three high density and two rural public health jurisdictions                                                                                                                                                                                                                                                                                                                                                                   |



|                                                                 |                                                                                                                                                                                                  |
|-----------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Outputs</b>                                                  |                                                                                                                                                                                                  |
| <b>Output Performance Measure</b>                               | # of clinics located in three high density and two rural public health jurisdictions that agree to implement the mass prophylaxis campaign                                                       |
| <b>Output Target</b>                                            | 5 clinics located in three high density and two rural public health jurisdictions that agree to implement the mass prophylaxis campaigns                                                         |
| <b>Immediate Outcome *</b>                                      | Increase capacity of clinics to implement mass prophylaxis campaigns Each site Identifies weaknesses in exercise planning and implementation efforts and takes corrective                        |
| <b>Immediate Outcome Performance Measure*</b>                   | Each site Identifies weaknesses in exercise planning and implementation efforts and takes corrective actions                                                                                     |
| <b>Immediate Outcome Target*</b>                                | Corrective action taken for at least 2 weaknesses identified during the exercise                                                                                                                 |
| <b>Progress Report- To be Reported Mid Year and End of Year</b> |                                                                                                                                                                                                  |
| <b>As of</b>                                                    | 2/15/2007                                                                                                                                                                                        |
| <b>Updates on Output Measures</b>                               | 3 clinics located in three high density jurisdictions agree to implement the mass prophylaxis campaigns                                                                                          |
| <b>Barriers</b>                                                 | Difficulty in collaborating with 2 clinics located in rural public health jurisdictions due to challenges in the availability of communication technology available to reach out to these areas. |

Note: \*Grantees only need to report on **Outputs, Output Performance Measures and Output Targets. They are not required to report Immediate Outcomes, Outcome Performance Measures and Outcome Targets.**

|                                                                                                                                                                          |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Example 2</b>                                                                                                                                                         |
| <b>CDC Goal: Pandemic Influenza Preparedness Goal 6: Control</b>                                                                                                         |
| <b>Target Capability: Mass Prophylaxis</b>                                                                                                                               |
| <b>CDC Performance Measure: Measure 2, Seasonal Flu Clinic: Percent of estimated patient throughput actually achieved for each shift during mass vaccination clinic.</b> |

|                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Critical Task: Develop and test an antiviral drug distribution plan describing the receipt, intrastate distribution, storage, security, monitoring, allocation, administration and use of antiviral drugs provided via the Strategic National Stockpile (SNS) or state stockpiles as appropriate.</b> |                                                                                                                                                                                                                                                                          |
| Name of Action Item: Develop a plan for receipt and intrastate distribution of antiviral drugs provided.                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                          |
| What                                                                                                                                                                                                                                                                                                     | Purpose of the Action Item<br>Develop a scalable plan for receipt and intrastate distribution of antiviral drugs to health care settings provided via SNS or state stockpile                                                                                             |
| Who                                                                                                                                                                                                                                                                                                      | Target audience<br>Health care settings including hospitals, skilled nursing facilities, community health centers and pharmacies.                                                                                                                                        |
|                                                                                                                                                                                                                                                                                                          | Stakeholders critical to success of the project<br>State health departments, local health jurisdictions, security/law enforcement, state homeland security agency, health care sector and other partners selected from the Pandemic Influenza Planning Committee Roster. |
|                                                                                                                                                                                                                                                                                                          | Who is responsible for the Outputs<br>State and local health departments                                                                                                                                                                                                 |
| When                                                                                                                                                                                                                                                                                                     | Time period of project<br>From late September 2006 thru September 2007                                                                                                                                                                                                   |
| Where (addresses reach)                                                                                                                                                                                                                                                                                  | Venue, location, etc.<br>State health department will develop an intrastate distribution plan that covers atleast 2 metropolitan statistical areas                                                                                                                       |
| Why                                                                                                                                                                                                                                                                                                      | Rationale<br>To ensure that local public health jurisdictions are better prepared to coordinate activities associated with the distribution of anti-virals in the event of a influenza pandemic                                                                          |
| <b>Success Factors</b>                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                          |
| <b>Outputs</b>                                                                                                                                                                                                                                                                                           | A scalable action plan that outlines how antivirals will be distributed from the state public health department to health care facilities including hospitals, skilled nursing facilities, community health centers and pharmacies.                                      |
| <b>Output Performance Measure</b>                                                                                                                                                                                                                                                                        | % of stakeholders that agree to and sign off on the finalized plan                                                                                                                                                                                                       |
| <b>Output Target</b>                                                                                                                                                                                                                                                                                     | 80 % of stakeholders agree and sign off on the finalized plan.                                                                                                                                                                                                           |
| <b>Immediate Outcome *</b>                                                                                                                                                                                                                                                                               | Increase capacity of state public health department to distribute anti-virals to local health care facilities including hospitals, skilled nursing facilities, community health centers and pharmacies.                                                                  |

|                                                                 |                                                                                                                                                                            |
|-----------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Immediate Outcome Performance Measure*</b>                   | # of external stakeholder groups with expertise in planning that approve its feasibility                                                                                   |
| <b>Immediate Outcome Target*</b>                                | At least 2 external stakeholder groups with expertise in planning approve the plan's feasibility.                                                                          |
| <b>Progress Report- To be Reported Mid Year and End of Year</b> |                                                                                                                                                                            |
| <b>As of</b>                                                    | 2/15/2007                                                                                                                                                                  |
| <b>Updates on Output Measures</b>                               | 50 % of stakeholders have signed off on the finalized plan                                                                                                                 |
| <b>Barriers</b>                                                 | Difficulty in setting up meetings with the remaining 30% stakeholders due to scheduling conflicts and change in leadership/point of contact at a number of these settings. |

**Note: \*Grantees only need to report on Outputs, Output Performance Measures and Output Targets. They are not required to report Immediate Outcomes, Outcome Performance Measures and Outcome Targets.**

## Attachment E

The following table outlines Step by Step Instructions for developing 2006 Pandemic Influenza Work Plan

| #  | STEP                                           | DESCRIPTION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|----|------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. | Pandemic Influenza Planning<br>Self Assessment | Conduct a follow up self assessment in Pandemic Influenza Planning (utilizing Phase 1 assessment tools: Attachment 4a, Self Assessment- State Public Health, Attachment 4b, Self Assessment-Local Public Health, and Attachment 4c- Self Assessment-Local Public Health Totals).                                                                                                                                                                                                                                                                                                                                                      |
| 2. | Analyzing results from the<br>Assessment       | Synthesize the results of updated state Pandemic Influenza Assessment data and local Pandemic Influenza Assessment data.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 3. | Identifying Gaps in Critical<br>Tasks          | For each of the nine Target Capabilities, develop a list of gaps as identified by the results of the data synthesis.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 4. | Prioritizing Work Plan Content                 | Develop a Work Plan for addressing Critical Tasks identified as 'gaps' in Step 1 for the following Target Capabilities:<br><br>1. Planning<br>2. Medical Surge<br>3. Mass Prophylaxis<br>4. Isolation and Quarantine<br>5. Communication<br><br>It is mandatory for Recipients to address Target Capabilities (1-4) because they correspond to the three priorities as highlighted in the Pandemic Flu Guidance outlined below. In addition, it is mandatory for Recipients to address the Target Capability for Communication because it ties in directly with the Performance Measure that relates to PHIN standards/certification. |

|                                                              |                                                               | <table><tr><th>Priorities for Pandemic Flu Guidance</th><th>Target Capability</th></tr><tr><td>State and Local Pandemic Influenza Preparedness Assessments,</td><td>Planning</td></tr><tr><td>Pandemic Exercise Program,</td><td>Medical Surge<br/>Mass Prophylaxis<br/>Isolation and Quarantine</td></tr><tr><td>Antiviral Drug Distribution Plan.</td><td>Mass Prophylaxis</td></tr><tr><td>PHIN Performance Measure</td><td>Communication</td></tr></table> <p>Prioritize the four remaining Target Capabilities based on the number of gaps identified in the assessment done in Step 1.</p> <table><tr><th>Target Capability</th></tr><tr><td>Epidemiological Surveillance and Investigation</td></tr><tr><td>Public Health Laboratory Testing</td></tr><tr><td>Emergency Public Information and Warning</td></tr><tr><td>Community Preparedness and Participation</td></tr></table> | Priorities for Pandemic Flu Guidance | Target Capability | State and Local Pandemic Influenza Preparedness Assessments, | Planning | Pandemic Exercise Program, | Medical Surge<br>Mass Prophylaxis<br>Isolation and Quarantine | Antiviral Drug Distribution Plan. | Mass Prophylaxis | PHIN Performance Measure | Communication | Target Capability | Epidemiological Surveillance and Investigation | Public Health Laboratory Testing | Emergency Public Information and Warning | Community Preparedness and Participation |
|--------------------------------------------------------------|---------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|-------------------|--------------------------------------------------------------|----------|----------------------------|---------------------------------------------------------------|-----------------------------------|------------------|--------------------------|---------------|-------------------|------------------------------------------------|----------------------------------|------------------------------------------|------------------------------------------|
| Priorities for Pandemic Flu Guidance                         | Target Capability                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                      |                   |                                                              |          |                            |                                                               |                                   |                  |                          |               |                   |                                                |                                  |                                          |                                          |
| State and Local Pandemic Influenza Preparedness Assessments, | Planning                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                      |                   |                                                              |          |                            |                                                               |                                   |                  |                          |               |                   |                                                |                                  |                                          |                                          |
| Pandemic Exercise Program,                                   | Medical Surge<br>Mass Prophylaxis<br>Isolation and Quarantine |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                      |                   |                                                              |          |                            |                                                               |                                   |                  |                          |               |                   |                                                |                                  |                                          |                                          |
| Antiviral Drug Distribution Plan.                            | Mass Prophylaxis                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                      |                   |                                                              |          |                            |                                                               |                                   |                  |                          |               |                   |                                                |                                  |                                          |                                          |
| PHIN Performance Measure                                     | Communication                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                      |                   |                                                              |          |                            |                                                               |                                   |                  |                          |               |                   |                                                |                                  |                                          |                                          |
| Target Capability                                            |                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                      |                   |                                                              |          |                            |                                                               |                                   |                  |                          |               |                   |                                                |                                  |                                          |                                          |
| Epidemiological Surveillance and Investigation               |                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                      |                   |                                                              |          |                            |                                                               |                                   |                  |                          |               |                   |                                                |                                  |                                          |                                          |
| Public Health Laboratory Testing                             |                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                      |                   |                                                              |          |                            |                                                               |                                   |                  |                          |               |                   |                                                |                                  |                                          |                                          |
| Emergency Public Information and Warning                     |                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                      |                   |                                                              |          |                            |                                                               |                                   |                  |                          |               |                   |                                                |                                  |                                          |                                          |
| Community Preparedness and Participation                     |                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                      |                   |                                                              |          |                            |                                                               |                                   |                  |                          |               |                   |                                                |                                  |                                          |                                          |
| 5.                                                           | Developing Work Plan Content and Success Factors              | <p>Attachment D provides a framework that inductively describes measurable and time phased Action Items which lead to the completion of Critical Tasks which in turn lead to the attainment of the Target Capabilities. This attachment also provides examples of how this framework can be used to develop work plans for two sample Action Items.</p> <p>This framework requires that Recipient Action Items be defined such that they are time phased and measurable using Outputs. This facilitates the tracking and monitoring of progress in achieving Action Items and their associated</p>                                                                                                                                                                                                                                                                                        |                                      |                   |                                                              |          |                            |                                                               |                                   |                  |                          |               |                   |                                                |                                  |                                          |                                          |

|    |                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|----|----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    |                            | <p>Critical Tasks and Target Capabilities.</p> <p>Using this approach, Recipients will develop one or more Action Items for Critical Tasks (with gaps) that fall under one of the five Target Capabilities identified in Step 4, (five priority Capabilities). Each Action Item includes a description of its purpose, target audience, major stakeholders/partners, time period, venue/location and rationale. In addition, each Action Item is associated with a set of success factors at the Output level (Note: While the framework provides Immediate Outcome measures, Grantees are only required to provide measures at the Output level). While multiple Action Items may be required to address a Critical Task in its entirety, Recipients are only required to define one Action Item for each Critical Task where a gap has been identified.</p> <p>Recipients will submit in their applications, a prioritized list of the remaining four Target Capabilities not included in the selections above.</p> |
| 6. | Implementing the Work Plan | <p>In year 1, Recipients will implement Action Items described in their Work Plan for the five Target Capabilities identified above.</p> <p>In year 2 recipients will prioritize all Critical Tasks for the next two priority Target Capabilities, create a work plan and implement Action Items as described in the work plan for the next two priority Target Capabilities (in addition to any pending work remaining from year 1).</p> <p>In year 3 recipients will prioritize all Critical Tasks for the remaining two Target Capabilities, create a work plan and implement Action Items as described in the work plan in addition to any pending work remaining from years 1 and 2.</p> <p>All Action Items and associated Critical Tasks and Target Capabilities will need to be accomplished within three years; with ongoing maintenance required.</p>                                                                                                                                                       |
| 7. | Reporting Progress         | <p>For each Action Item described in the Work Plan, Recipients will provide</p> <ul style="list-style-type: none"> <li>• Updates regarding the extent to which Output measures have been</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

|    |                                                      |                                                                                                                                                                             |
|----|------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    |                                                      | achieved (as part of their mid year and end of year progress reports). <ul style="list-style-type: none"><li>• Barriers encountered in achieving the Action Item.</li></ul> |
| 8. | Reporting Standard Performance Measures <sup>9</sup> | Recipients will indicate progress made towards achieving Target Capabilities by submitting standard Performance Measures as outlined in Attachment A.                       |

<sup>9</sup> Standard Performance Measures are developed by CDC to consistently track the attainment of Target Capabilities across recipients.





# Exhibit O



Washington, D.C. 20201

OCT 24 2007

**TO:** Dr. Julie L. Gerberding, M.D., M.P.H.  
Director  
Centers for Disease Control and Prevention

**FROM:** Daniel R. Levinson *Daniel R. Levinson*  
Inspector General

**SUBJECT:** Memorandum Report—Laboratory Preparedness for Pandemic Influenza,  
OEI-04-07-00670

This memorandum report provides information on laboratory pandemic influenza preparedness as requested in April 2007 by officials at the Centers for Disease Control and Prevention (CDC).

The Office of Inspector General (OIG) surveyed State public health laboratory officials in June 2007 about the extent to which they conducted the eight critical tasks for public health laboratory testing as required by the Pandemic Influenza Guidance Supplement to the 2006 Public Health Emergency Preparedness Cooperative Agreement, Phase II (the Guidance).<sup>1</sup>

All States reported that their public health laboratories performed the first two critical tasks, to conduct year-round influenza testing and to detect and subtype influenza viruses.<sup>2</sup> Although not specifically required by the Guidance, all States reported public health laboratory capability to subtype H5 influenza.<sup>3</sup> The H5 subtyping test is currently only available to public health laboratories. Consistent with this, most States reported that they have no sentinel laboratory capability to subtype H5 influenza.<sup>4</sup> However, this capability may be necessary to meet increased testing needs during an H5 influenza pandemic.

All States reported that their public health laboratories did not perform at least one of the six remaining critical tasks. For the tasks involving both public health and clinical laboratories,

<sup>1</sup> The eight critical tasks are outlined in Attachment B under Pandemic Influenza Preparedness Goal 3: Detect and Report, Target Capability 3B. The Guidance is available online at <http://www.bt.cdc.gov/planning/coopagreement/pdf/phase2-panflu-guidance.pdf>. Accessed August 27, 2007.

<sup>2</sup> There are different types of influenza viruses (e.g., H1, H3, H5). Subtyping refers to the ability to distinguish one type of influenza from another.

<sup>3</sup> The H5 strain of influenza normally infects birds, but it has the potential to cause a human pandemic.

<sup>4</sup> Sentinel laboratories conduct initial screenings of biological specimens and refer suspicious specimens to public health laboratories.

Page 2 – Dr. Julie L. Gerberding, M.D., M.P.H.

States reported performing the required activities for public health laboratories to a greater extent than for clinical laboratories.<sup>5</sup>

## **BACKGROUND**

### **Funding for Pandemic Influenza Preparedness and Response**

In 2005, Congress appropriated \$350 million for upgrading State and local capacity to prepare for and respond to an influenza pandemic. These funds have been awarded by the Department of Health and Human Services (HHS) in phases.<sup>6</sup> In March 2006, CDC awarded \$100 million (Phase I) to 62 jurisdictions to identify gaps in their preparedness based on 60 critical tasks.<sup>7 8</sup> An updated version of these critical tasks is included in Attachment B of the Guidance. As of July 2006, CDC had awarded an additional \$225 million to the same jurisdictions to address these preparedness gaps (Phase II). CDC plans to award the remaining \$25 million through competitive grants to eligible recipients. Awardees are expected to complete tasks supported by the Guidance in 3 years, ending in 2009. By 2009, CDC expects that awardees should be fully prepared to respond to and control an influenza pandemic.<sup>9</sup>

In August 2007, the Secretary of HHS announced another \$75 million for pandemic influenza preparedness.<sup>10</sup> These grants will supplement funds dedicated to strengthen the ability of the Nation's health care community to respond to bioterrorism, infectious diseases, and natural disasters.

### **Public Health Laboratory Testing Requirements for Pandemic Influenza Preparedness**

The eight required critical tasks for public health laboratory testing as specified by the Phase II Guidance are to:

1. maintain the ability to test for influenza viruses year-round;
2. perform polymerase chain reaction (PCR) testing for rapid detection and subtyping of influenza viruses;
3. electronically exchange specimen-level data among clinical laboratories, the State public health laboratory, and CDC;

<sup>5</sup> The tasks involving both clinical and public health laboratories are critical tasks 3, 5, 6, and 7.

<sup>6</sup> Emergency Supplemental Appropriations Act To Address Hurricanes in the Gulf of Mexico and Pandemic Influenza Act, 2006, Pub. L. No. 109-148, Division B, Title II, Chapter 6 (Dec. 30, 2005).

<sup>7</sup> These funds supplement the 2006 Public Health Emergency Preparedness Cooperative Agreement. Available online at <http://www.bt.cdc.gov/planning/coopagreement/pdf/fy06announcement.pdf>. Accessed August 27, 2007.

<sup>8</sup> The 62 jurisdictions are the 50 States, the District of Columbia, the cities of Chicago and New York, Los Angeles County, Puerto Rico, the U.S. Virgin Islands, and the 6 Pacific Basin jurisdictions.

<sup>9</sup> The Guidance, page 4, available online at <http://www.bt.cdc.gov/planning/coopagreement/pdf/phase2-panflu-guidance.pdf>. Accessed August 27, 2007.

<sup>10</sup> News Release available online at <https://www.hhs.gov/news/press/2007pres/08/pr20070830a.html>. Accessed September 3, 2007.

Page 3 – Dr. Julie L. Gerberding, M.D., M.P.H.

4. institute surveillance for influenza-like illness among laboratory personnel working with novel influenza viruses;
5. develop and exercise an operational plan to augment the capacity of public health and clinical laboratories to meet the needs of the jurisdiction during an influenza pandemic;
6. assess all public health and clinical laboratory influenza diagnostic testing proficiency and adherence to biosafety containment and biomonitoring protocols at least annually;
7. test the knowledge and competency of frontline clinicians and laboratory personnel with regard to:
  - a. protocols for safe specimen collection and testing,
  - b. the way in which and the person to whom a potential case of novel influenza should be reported, and
  - c. mechanisms for submitting specimens to referral laboratories; and
8. determine how hospitals and health care systems will use systems and communication tools to report information to public health and response partners with an emphasis on regional hospital coordination.

### **Role of Clinical Laboratories in Public Health Preparedness and Response**

As of June 2007, there were 210 public health laboratories in the U.S.<sup>11</sup> According to the Association of Public Health Laboratories, disease prevention, control, and surveillance should collectively represent a core function of State public health laboratories.<sup>12 13</sup> However, privately owned clinical laboratories, which are not under the control of State public health laboratories, play a key role in States' ability to perform these activities, especially surveillance.

Clinical laboratories are often the first line of defense in a public health response because they perform diagnostic tests ordered by physicians and may be the first to identify the causes of illnesses in communities. However, not all clinical laboratories have the capacity to conduct initial screenings and refer suspicious specimens to a reference laboratory, usually the State public health laboratory, to confirm the presence of public health threats. Clinical laboratories that do have these capabilities are known as sentinel laboratories.<sup>14</sup>

---

<sup>11</sup> Clinical Laboratory Improvement Amendments (CLIA) Update, Division of Laboratory Services, Centers for Medicare & Medicaid Services, Laboratories by Type of Facility, June 2007. Available online at <http://www.cms.hhs.gov/CLIA/downloads/factype.pdf>. Accessed September 17, 2007.

<sup>12</sup> "Core Functions and Capabilities of State Public Health Laboratories," p. 6. Available online at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5114a1.htm>. Accessed August 29, 2007.

<sup>13</sup> Public health surveillance is the ongoing collection, analysis, and interpretation of health data to improve health and safety.

<sup>14</sup> Forty-nine States use this definition of sentinel laboratory in the pandemic influenza context.

Page 4 – Dr. Julie L. Gerberding, M.D., M.P.H.

### **Related Work**

OIG is conducting a study of laboratory preparedness for bioterrorism and other public health emergencies. We expect to issue a final report on those findings in early 2008.

## **METHODOLOGY**

### **Scope**

We surveyed officials in all 50 States and the District of Columbia (hereafter referred to as States) about the extent to which they conducted the eight critical tasks for public health laboratory testing as required by the Guidance. Four of these critical tasks require coordination with clinical laboratories. We also asked the officials about public health and sentinel laboratory capability to subtype H5 influenza, as well as the type of preparedness exercises conducted by State public health laboratories (i.e., tabletop or full-scale).

### **Data Collection**

We contacted the Cooperative Agreement coordinators in all States to inform them about our survey and to request the names of the most appropriate respondents. In most cases, we were referred to the State laboratory director or the bioterrorism coordinator. We sent an electronic mail survey to these public health laboratory officials identified by the Cooperative Agreement coordinator in each State and had a 100-percent response rate.

### **Data Analysis**

We transferred State responses to our survey into an electronic database. Using the database, we determined the total number of States that reported performing each of the eight critical tasks. Where appropriate, we determined whether the State conducted an activity for both State public health and clinical laboratories.

### **Limitations**

We asked State public health laboratory officials the extent to which they conducted the eight critical tasks for public health laboratory testing as required by the Guidance. However, responsibility for some of these tasks may fall under another State or non-State entity (e.g., the Office of Emergency Preparedness and Response or the College of American Pathologists, respectively). In addition, we did not collect supporting documentation to verify State responses to our survey, and we did not ask States about the performance measures associated with the eight critical tasks. Finally, our survey determined the extent to which State public health laboratories met Guidance requirements to include clinical laboratories in their preparedness planning. We did not directly survey clinical laboratory officials to determine whether they had performed pandemic influenza preparedness activities independent of the State public health laboratories.

This study was conducted in accordance with the “Quality Standards for Inspections” issued by the President’s Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

Page 5 – Dr. Julie L. Gerberding, M.D., M.P.H.

## RESULTS

### ***Critical task 1: All States reported that they conduct year-round influenza testing***

Year-round influenza testing can detect the emergence of influenza viruses outside the normal influenza season. This early detection may lead to a faster public health response to a potential pandemic influenza outbreak. All 51 States reported that their public health laboratories conduct year-round influenza testing.

### ***Critical task 2: All States reported the capability to perform PCR to detect and subtype influenza, but sentinel laboratory capability to subtype H5 influenza is limited or unknown***

The H5 strain of influenza infects birds but does not typically infect humans. However, it has caused human deaths and has the potential to evolve into a human pandemic strain.

Although not specifically required by the Guidance, all 51 States reported public health laboratory capability to use PCR to subtype the H5 influenza strain. The H5 subtyping test is currently only available to public health laboratories. Consistent with this, 44 of 51 States reported that they have no sentinel laboratories with the capability to perform H5 influenza subtyping, and 4 States reported that they did not know whether sentinel laboratories in their State had H5 influenza subtyping capability. However, this capability may be necessary to meet increased testing needs during an H5 influenza pandemic.

### ***Critical task 3: States reported that they electronically exchange influenza data with CDC and public health laboratories to a greater extent than with clinical laboratories***

Public health officials often rely on patient-level data from clinical laboratories to determine an appropriate response to a public health event. Similarly, clinical laboratories often rely on State and national data from public health laboratories and CDC to determine appropriate laboratory testing.

Almost 90 percent of States (45 of 51) reported exchanging electronic influenza data with CDC. Similarly, almost 90 percent of States (45 of 51) reported either that they exchanged electronic influenza data within the State public health laboratory system (24 of the 45 States) or that this requirement was not applicable (21 of the 45 States). For example, this requirement is not applicable in a State with only one public health laboratory.

However, only 35 percent of States (18 of 51) reported electronic influenza data exchange between public health laboratories and clinical laboratories.



Page 6 – Dr. Julie L. Gerberding, M.D., M.P.H.

Table 1 shows the number of States reporting that the State public health laboratories exchanged electronic influenza data.

**Table 1**

| <b>Number of States Reporting That Public Health Laboratories Electronically Exchanged Influenza Data</b> |            |                       |
|-----------------------------------------------------------------------------------------------------------|------------|-----------------------|
| <b>Entities With Which the Public Health Laboratories Electronically Exchanged Influenza Data</b>         | <b>Yes</b> | <b>Not Applicable</b> |
| CDC                                                                                                       | 45         | 0                     |
| Other State Public Health Laboratories                                                                    | 24         | 21                    |
| Clinical Laboratories                                                                                     | 18         | 0                     |

***Critical task 4: Over half of all States reported that they instituted surveillance for influenza-like illness among laboratory personnel at risk for atypical influenza***

Laboratory personnel who conduct influenza testing are at risk of developing illness from seasonal influenza, as well as atypical influenza present during a pandemic. The earlier illness is detected, the earlier the State may take action and attempt to contain its spread. Sixty-two percent of States (32 of 51) reported that they conduct surveillance for influenza-like illnesses among laboratory personnel at risk of developing atypical influenza.

***Critical task 5: States reported that they conduct pandemic influenza preparedness exercises in public health laboratories to a greater extent than in clinical laboratories***  
Preparedness exercises present public health personnel hands-on practice of emergency plans and procedures. Exercises may also identify potential response weaknesses in advance of an actual event.

Eighty-two percent of States (42 of 51) reported developing operational plans to augment public health laboratory capacity during an influenza pandemic. Forty-three percent of States (22 of 51) reported conducting tabletop exercises of their operational plans, and 20 percent of States (10 of 51) reported conducting full-scale exercises.<sup>15</sup>

In contrast, 55 percent of States (28 of 51) reported developing operational plans for clinical laboratory capacity. Thirty-one percent of States (16 of 51) reported conducting tabletop exercises of plans to meet the increased need for clinical laboratory testing capacity during an

---

<sup>15</sup> In a tabletop exercise, participants respond to a simulated emergency without time constraints from an office environment. Tabletop exercises are intended to evaluate plans and answer questions about coordination and assignments of responsibility. In a full-scale exercise, participants respond to a simulated emergency under time constraints conditions just as they would in a real-world event. Full-scale exercises are intended to identify problems that may arise in executing a plan.

Page 7 – Dr. Julie L. Gerberding, M.D., M.P.H.

influenza pandemic, and less than 10 percent of States (5 of 51) reported conducting full-scale exercises.

Table 2 shows the number of States reporting that they have developed operational plans to augment laboratory capacity in an influenza pandemic and have tested those plans through tabletop or full-scale exercises.

**Table 2**

| <b>Number of States Reporting That They Have Developed and Tested Plans To Augment Laboratory Capacity</b> |                                          |                                     |
|------------------------------------------------------------------------------------------------------------|------------------------------------------|-------------------------------------|
| <b>Pandemic Influenza Preparedness Activity</b>                                                            | <b>Public Health Laboratory Capacity</b> | <b>Clinical Laboratory Capacity</b> |
| Developed operational plan                                                                                 | 42                                       | 28                                  |
| Exercised operational plan – tabletop                                                                      | 22                                       | 16                                  |
| Exercised operational plan – full-scale                                                                    | 10                                       | 5                                   |

***Critical task 6: States reported that they conduct annual assessments of influenza-related practices in public health laboratories to a greater extent than in clinical laboratories***

Annual assessments of laboratory practices help to ensure that laboratory personnel are using the most current practices in responding to an influenza outbreak.

Depending on the laboratory practice, 65 percent to 82 percent of States (33 to 42 States) reported that the State public health laboratories conduct annual assessments of influenza-related activities in public health laboratories. However, only 12 percent to 20 percent of States (6 to 10 States) reported that the State public health laboratories conduct the same annual assessments in clinical laboratories.

Table 3 shows specific influenza-related practices and the corresponding number of States that reported conducting at least annual assessments in public health and clinical laboratories.

**Table 3**

| <b>Number of States Reporting That the Public Health Laboratories Annually Assess Influenza-Related Practices</b> |                                             |                                        |
|-------------------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------------------------|
| <b>Areas State Public Health Laboratories Assess Annually</b>                                                     | <b>Public Health Laboratory Assessments</b> | <b>Clinical Laboratory Assessments</b> |
| Influenza diagnostic testing proficiency                                                                          | 42                                          | 10                                     |
| Adherence to influenza biosafety containment                                                                      | 42                                          | 7                                      |
| Adherence to influenza biomonitoring protocols                                                                    | 33                                          | 6                                      |

Page 8 – Dr. Julie L. Gerberding, M.D., M.P.H.

Twenty-one States reported that they do not assess clinical laboratories on the activities specified in the Guidance because this function is performed by other organizations (e.g., the College of American Pathologists or the Centers for Medicare & Medicaid Services in its oversight of the Clinical Laboratory Improvement Act).

**Critical task 7: States reported that they conduct tests on pandemic influenza preparedness activities for frontline laboratory personnel to a greater extent than for frontline clinicians** Frontline clinicians and laboratory personnel who perform diagnostic tests play a significant role in public health emergency response. They may be the first to identify and trigger a State’s response to illness in communities.

Depending on the laboratory practice, 53 percent to 73 percent of States (27 to 37 States) reported that their public health laboratories test frontline laboratory personnel on pandemic influenza preparedness activities (e.g., protocols for safe specimen collection and testing and referring potential cases of novel influenza).

Less than 25 percent of States (11 of 51) reported that their public health laboratories test clinicians on how to submit suspected influenza specimens to a testing laboratory. Even fewer States (7 of 51) reported that their public health laboratories test clinicians on the person they should contact when referring a potential case of novel influenza or on protocols for safe specimen collection or testing.

Table 4 lists specific pandemic influenza preparedness activities, along with the number of States reporting that their public health laboratories test each activity for frontline laboratory personnel and clinicians.

**Table 4**

| <b>Number of States Reporting That the Public Health Laboratories Test Influenza Preparedness Activities for Laboratory Personnel and Clinicians</b> |                                     |                          |
|------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|
| <b>Preparedness Activity Tested</b>                                                                                                                  | <b>Laboratory Personnel Testing</b> | <b>Clinician Testing</b> |
| Protocols for safe specimen collection                                                                                                               | 28                                  | 7                        |
| Protocols for safe specimen testing                                                                                                                  | 32                                  | 7                        |
| How to refer a potential case of novel influenza                                                                                                     | 27                                  | 8                        |
| Person to contact when referring a potential case of novel influenza                                                                                 | 29                                  | 7                        |
| How to submit specimens to a referral laboratory                                                                                                     | 37                                  | 11                       |

Page 9 – Dr. Julie L. Gerberding, M.D., M.P.H.

Two States reported that they do not test frontline laboratory personnel or clinicians because they receive pandemic influenza preparedness testing or training through a third party (e.g., the Health Resources and Services Administration or the State Office of Epidemiology). In addition, one State reported that because public health laboratory personnel are not responsible for collecting specimens or referring potential cases of novel influenza, they are not tested on these tasks.

***Critical task 8: Twenty-five percent of States reported that they determine how hospitals and health care systems would use pandemic influenza communication tools***

Accurate communication during a health event enables public health officials to determine the optimal course of action in responding to an event. States should formalize communication procedures in advance to avoid confusion and miscommunication during an actual event.

Twenty-five percent of States (13 of 51) reported that their State public health laboratories have determined how hospitals and health care systems would use pandemic influenza communication tools to report information to public health and response partners during an event. Of these 13 States, 6 further reported that their public health laboratories have determined how communication tools would be used for regional hospital coordination.

Twenty-seven percent of States (14 of 51) reported that they have not determined how hospitals and health care systems would use communication tools because this function is carried out by other State entities (e.g., the Office of Public Health Emergency Preparedness or the Bureau of Epidemiology).

## **CONCLUSION**

Pandemic influenza preparedness projects supported by Phase II Guidance funding should be completed in 3 years, ending in 2009. Most State public health laboratories reported that they have already performed some of the requirements specified by the Guidance. For example, all States reported that their public health laboratories performed the requirement for year-round influenza testing. In addition, over half of States reported instituting surveillance for influenza-like illness among laboratory personnel. Although not specifically required by the Guidance, all States also reported public health laboratory capability to subtype H5 influenza, but sentinel laboratory capability to subtype H5 influenza is limited or unknown. However, this capability may be necessary to meet increased testing needs during an H5 influenza pandemic.

Our survey results demonstrate that opportunities exist to improve public health laboratory coordination with clinical laboratories. For the critical tasks involving both public health and clinical laboratories, States reported performing the required activities for public health laboratories to a greater extent than for clinical laboratories.

Clinical laboratories will likely be among the first to detect an influenza outbreak because they perform diagnostic testing ordered by clinicians. Therefore, coordination between State public

Page 10 – Dr. Julie L. Gerberding, M.D., M.P.H.

health and clinical laboratory officials is critical to decrease the time needed to detect and report a pandemic influenza outbreak.

If you have any questions about this memorandum report, please do not hesitate to contact me or one of your staff may contact Claire Barnard, Director of External Affairs, at (202) 205-9523 or through e-mail [[Claire.Barnard@oig.hhs.gov](mailto:Claire.Barnard@oig.hhs.gov)]. To facilitate identification, please refer to memorandum report number OEI-04-07-00670 in all correspondence.

cc: Rear Admiral W. Craig Vanderwagen, M.D.  
Assistant Secretary for Preparedness and Response